

**BARRIERS AND FACILITATORS OF LEAN SIX SIGMA IMPLEMENTATION
IN IRISH PHARMACEUTICAL COMPANIES**

Research dissertation presented in partial fulfilment of the requirements
for the degree of
MSc in International Pharmaceutical Business Management
Griffith College Cork

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26th August 2019.

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I certify that the dissertation entitled:

Barriers and Facilitators of Lean Six Sigma In Irish Pharmaceutical Companies

Submitted for the degree of: **MSc in Programme Name here** is the result of my own work and that where reference is made to the work of others, due acknowledgment is given.

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DEDICATION

I dedicate this work to God almighty for his grace and to my family for their endless support.

ACKNOWLEDGEMENT

I want to thank my supervisor Dr. Caroline Hurley for her support, guidance and cooperation throughout my research.

Special thanks to my family, David (Dad) for his daily inspiration, calls and care, to Flora (Mum) for been a listening ear and a great adviser, to Christopher and Caleb (Brothers) for making me see the humour and simplicity in every difficulty, to Justice (Brother) who made it possible for me to pursue and attend this Master's program, I am forever grateful.

I would like to thank all employees who participated in my research.

To all my friends and extended family, thank you for your support.

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LIST OF ABBREVIATIONS

Abbreviation	Description
LSS	Lean Six Sigma
R&D	Research and Development
SME's	Small or Medium Enterprises
CSF	Critical Success Factor
JIT	Just in Time
GSK	GlaxoSmithKline
TQM	Total Quality Management
cGMP	Good Manufacturing Practice
DMADV	Define, Measure, Analyse, Design, Verify.

ABSTRACT

BARRIERS AND FACILITATORS OF LEAN SIX SIGMA IMPLEMENTATION IN IRISH PHARMACEUTICAL COMPANIES

OJUEDERIE ESEOGHENE RACHEAL

The research set out to interrogate the barrier and facilitators of Lean Six Sigma Implementation in Irish Pharmaceutical companies. To this end, the main objectives was to identify the factors that hindered and facilitated the successful implementation of; Lean Six Sigma in Irish pharmaceutical companies. To achieve its objectives, the qualitative method was adopted and data were sourced through primary and secondary methods with the research interview acting as a main source of data. A purposive sample of participants (n=5) were interviewed to get their perception of the barriers and facilitators to Lean Six Sigma in their organization, the participants were employees of five different pharmaceutical companies in Ireland. Thematic analysis was applied to interpret the data while comparing the results to that of similar studies. The study found out that the major factors that acted as barriers to the implementation of LSS in Irish pharmaceutical companies were the lack of finance to train the required personals to handle the program which led to a shortage of qualified manpower. In addition, adaptability to change, team work, the use of multiple tools and management commitment to LSS were identified as the most important facilitators to LSS. To this end, the study concludes that the major barrier to LSS in Irish pharmaceutical companies was a lack of understanding as to what LSS really is due to poor training tried to several other factors.

Keywords: Lean Six Sigma, Barriers, Facilitators, Implementation.

CHAPTER ONE

1. INTRODUCTION

1.1 OVERVIEW

In the rapid changing business environment due to Globalization and rise in new technologies, Pharmaceutical companies need to adapt to changes. The need for efficiency and cost reduction for a competitive edge in the industry drives this goal in this business environment (Leonard & Schneider, 2004). Due to the needs, many pharmaceutical enterprises are looking for a brand-new formidable approach to deal with the intricacies and gaps in the business environment, they strive continuously for process optimization to get customer retention and satisfaction, reduce cost, improve employee morale and get better product quality. Internal processes and operations are the primary focus of companies to achieve effective results.

1.1.1 Lean Six Sigma

Integration of Lean Six Sigma is one of the most current management tools which enhances organizational infrastructure which will gain competitive gain (Thangarajoo and Smith, 2015).

The fusion of Lean techniques with Six Sigma strategy, known as Lean sigma or Lean Six Sigma (LSS), has attracted interest from industries and academics (Snee, 2010). The purpose of this research is to identify the barriers and facilitators to Lean Six Sigma Implementation in Irish Pharmaceutical Companies.

Laureani and Anthony (2012) stated that LSS is a methodology for process improvement in business, which aims to boost efficiency of operations bettering speed, customer satisfaction, quality and speed by eliminating waste. LSS not only reduces process defects and waste, but also provides a framework for overall organizational culture change, integration of LSS may involve distinct thoughts, instruments and philosophies to be transferred.

LSS is a method that depends on a synergistic team effort for performance improvement by regularly getting rid of waste and variation reduction, It incorporates Six Sigma and

Lean manufacturing to cut out the 8 types of waste, which are as follows; Motion, Defects, Over Production, Inventory, Non-Utilized Talent, Waiting, Transportation, Extra-Processing (Antony, 2014).

LSS includes a pack of tools and concepts which are focused on continuous improvement of performances by eliminating waste systematically within production processes (Thangarajoo and Smith, 2015).

LSS manufacturing is a method that aims to diminish varieties of waste experienced in manufacturing cycle, as a result get better product quality, better customer value and get higher profits, LSS works on several levels of production, of which includes; production, customers' satisfaction and service, product quality, it is from the onset of purchase of raw materials from supplier to delivery of product to the final customer. Lean aims at decreasing activities that do not add value.

Lean Production has its history dated to the 1950's, where the Japanese motor manufacturer saw the need for efficiency in production, more components of Lean has been developed since then (Womack et al., 2007).

Six Sigma originated from Motorola in the 1980s, Six Sigma was used for regular improvement after it was used by General Electric (GE) Motor as an improvement action within the organization to preserve competitiveness (Eckes, 2002).

Six Sigma and Lean and their constraint have augmented the use of both approach, this has led to a Six Sigma and Lean methodology, which overcomes the limitation of the individual method when implemented as an entity (Timans *et al.*, 2011).

1.2 RESEARCH PURPOSE

LSS initiatives had been utilized by numerous businesses to power modern strategies inside their organizations to reap more overall performance with little assets and resources. LSS is well established in Pharmaceutical companies like GlaxoSmithKline, this method was implemented across the entire factory, and this led to cost savings of about £300 million through operation efficiencies (OE) in 2004 and the implementation

was over seen by an OE group, this was one of the strategy used by GSK to improve performance (GlaxoSmithKline, 2004). LSS utilized by GSK brought about reduction in operation cost, increase in productivity, waste reduction and activities that added value (Carleysmith, et al., 2009). Continuous Improvement has been a major interest for years and due to pressure and challenges pharmaceutical companies are facing, they have to perform effectively. Research by Koripadu & Subbaiah (2014) suggested that LSS systems can be used in solving problems and challenges to give efficiency and better profits.

Critical factors related to application of Lean management and Six Sigma Strategies were evaluated, the research carried out showed that the two variables which are considered important in organization of businesses, improves product quality and enhances productivity in pharmaceutical companies (Abdullah , et al., 2018). LSS was identified as a tool for continuous improvement and more research should be carried out on LSS.

Research by Raghunath & Jayathirtha (2013) provided an overview of barriers for applying and implementing Six sigma in SMEs, financial, organizational and technological limitations act as barriers to SMEs implementing Six Sigma, these barriers includes; Poor knowledge of Six Sigma, Insufficient coaching and training, Resistance from within the organization, Project for Six Sigma selected poorly, Inadequate resources, Poor organization and poor leadership structure, insufficient and missing data. There are lots of factors which can influence a hit adoption of lean implementation, for this reason, it is crucial to become aware of the most pertinent factors which are the CSFs. Studies conducted by (Achanga, et al., 2006) showed and identified the factors and facilitators that influences successful implementation of LSS, the important factors identified includes; involvement and commitment by top management, company's culture, education and training to increase knowledge, involvement of employees and application of methods and tools properly. This study analysed the success factors for Lean implementation but only took the views of either company managers or LSS certified professionals or staff, the findings of these studies do not collectively represent the point of view of all groups involved in implementing LSS as it focused on identifying what a particular group sees as facilitators for Lean Implementation

Research conducted by Richard, *et al.* (2018) targeted the implementation of Lean Six sigma in the Western Ireland manufacturing companies, the research had a qualitative and quantitative approach, where four manufacturing companies were targeted and the participants were validation engineers, LSS experts, R&D engineers, managers and quality engineers. their study showed commitment of top management, proper understanding of LSS tools, trainings and organizational cultural change were the facilitators of LSS, while cost, inadequate support from top management were the barriers, they further suggested the need for more detailed research study in a more focused sector and in the whole of Ireland for better comparison to other countries. Hence the need to evaluate the implementation of Lean Six Sigma in Irish Pharmaceutical Companies.

Furthermore, the researches carried out are either on Six Sigma or Lean manufacturing as a separate entity, their barriers and success factors, there appear to be no research exploring Lean and Six Sigma as a single methodology, while identifying the barriers and facilitators.

However, no research has been carried out to explore the barriers and facilitators of Lean and Six Sigma methodology implemented in Pharmaceutical Industries in Ireland. This research tries to tackle the gaps in the studies outlined above by conducting a study on the perception of staff on the facilitators and barriers of LSS implemented in Pharmaceutical organizations in Ireland to gain more insight, different and a rounded view from perspective of employees

1.3 SIGNIFICANCE OF THE STUDY

The study will help understand the perspective of employees and their view on LSS in Pharmaceutical Companies in Ireland, as well as help to recognize the barriers and facilitators of LSS implementation in their Companies.

The study and findings will be of great interest to academic research, add to existing literature and studies concerning decision making and reporting of LSS, the findings can

be used by Pharmaceutical Professionals and decision makers to gain more knowledge and insight on how to implement LSS, with the barriers and facilitators identified, knowing what areas need further enhancement and what areas are performing well to ensure the LSS initiative in the organization are sustainable and effective

1.4 RESEARCH OBJECTIVE

The aim of this research is to carry out a qualitative study on the facilitators and barriers that Pharmaceutical companies based in Ireland encounter while implementing LSS.

The research tries to comprehend employees' opinions on the subject empirically; the barriers that affect LSS implementation and facilitators of LSS implementation that are specific to their companies, the focus of this study was to:

- Identify the facilitators and success factors associated with LSS implementation.
- Identify the barriers associated with LSS implementation
- Investigate how Lean Six Sigma is implemented in the organization and its challenges.

The objective of the research is to collect opinions of employees engaged in LSS within their organization.

Major Research questions asked will be:

- How is Lean Six Sigma Implemented in Pharmaceutical organizations in Ireland?
- What factors have facilitated the implementation of LSS Pharmaceutical companies?
- What are the challenges the company could encounter in the implementation of Lean Six Sigma?

1.5 STRUCTURE OF THE STUDY

This research has 5 chapters including the Introduction. Chapter 2 examines a literature review on LSS pertaining to the research topic, chapter 3 shows the research methodology

and methods selected for this study purpose, which is qualitative method. Chapter 4 summaries and compares the findings from the qualitative study, also, discussion and interpretation of results are presented in this chapter. Lastly chapter 5 identifies contributions, limitation of this study and direction for future research.

CHAPTER 2

2. CRITICAL LITERATURE REVIEW

2.1 INTRODUCTION

The literature search was conducted using different approaches; general searching online, browsing secondary literature in my library, acquiring relevant literature from journals, peer-reviewed academic journals, articles, thesis and books read, broad search online.

EBSCO database host and Google scholar were searched to identify eligible grey literatures in July 2019. The search was restricted to publication dates, last twenty years, but there was no geographical and language limitation in the process of selection. Grey literature has been more specifically conceptualized in narrow and broad ways. Luzi (2000) conservatively defines it a kind of document generated at all government levels, company and academics in digital and print form; they are protected by intellectual property right, which are to be maintained by library holdings.

The following search terms were used; Lean Six Sigma in pharmaceutical industries, Lean Six Sigma implementation, Barriers and facilitators of Lean Six Sigma. The search was restricted to the first twelve pages of results, as eligible papers were identified as early as the first page but needed varieties of papers on the search term. The literature review's focus and goal is to comprehend the LSS research that has been undertaken, highlight the primary developments in the literature and to identify gaps where further study is required.

In total, 1000 papers describing the search terms were retrieved from grey and published literature. The researcher assessed these papers and checked for eligibility and linkage to the research topic. While interest in studies in the LSS region has grown in the last decade or so, in terms of variety and depth, the literature is light. The literature contains content; proposes conceptual frameworks for LSS implementation

In this Chapter, an overview of the following will be discussed; Six Sigma, Lean Manufacturing, LSS methodology, LSS tools, LSS in Pharmaceutical Industries, Implementation of LSS, Barriers and challenges faced during implementation of LSS and Facilitators of implementing LSS.

2.2 SIX SIGMA IN PHARMACEUTICAL INDUSTRY

Six Sigma is method formulated by an engineer at Motorola in the year 1986, by Bill Smith, the system used for business did not involve customer satisfaction, Motorola had suffered failures due to customers receiving too many failed products, there was a need to

change their manufacturing, services and sales to focus on customer satisfaction, hence Six Sigma was birthed (Larson, 2003).

Six Sigma has been defined from different perspectives, Divoky (2008) defined it as a methodology that incorporates elements of quality and augments its unique access to business environment.

Current developments in pharmaceutical industry would now be the ideal time to turn to six sigma principles. Before now, traditional management tools like manufacturing chart, quarterly chart and Gantt chart were used but this method does not prove effective compared to the six sigma (Itkin, 2008).

This means that the pharmaceutical industries have a lot to gain from the Six sigma. The Six sigma performance has been increased on daily basis in pharmaceutical companies as it focuses on the development and distribution of ideal products. (Noori and Latifi, 2018) One can also say that six sigma is a set of tools and techniques used in solving problems or improve process (Libutan, 2007)

Weinstein (2010) stated that Six Sigma is used for business development, so as to improve efficiency and effectiveness of operations, also to increase profitability. Six Sigma has helped a lot of companies in different industries to improve business process and improve profitability (Goldsby and Martichenko, 2014). Eli Lilly, Johnson & Johnson and Novartis are examples of pharmaceutical firms that have implemented Six Sigma (Stuckrath 2006). Though the pharmaceutical industry is extremely controlled to guarantee that businesses fulfil all regulatory agency demands, many key procedures do not fulfil today's market and customers requirement as drug development requires longer years before it can be commercialized. The use of Six Sigma is one of the prospective solutions to the problem pharmaceutical companies are facing, it challenges length product development lines (Cortada et al., 2004). Pharmaceutical companies implement Six Sigma in the R&D sector, so as to lower expenses, reduce marketing time and improve process and product quality (Johnson, 2006).

Six Sigma is a methodology of continuous improvement focused at reducing defects by using the model. Define-Measure-Analyse-Improve-Control (DMAIC) (Bicheno, 2006)

- D - Define objectives for improving the general process between your corporate strategy

and the requests of your customer (can also refer to your group and the organizations or people you support)

- M - Measure your current processes. Collect relevant data on your current processes and then use this data as a baseline for future comparisons.

- A - Analyse in the process your connection. To determine factors that can guarantee that you maintain the approach of your company in line with the requirements of your clients, it is essential to know the connection.

- I - Improve the process. Using analysis and other methods, it is essential to constantly enhance and optimize the process. One method that is frequently used is experimental design. (This is a method that can use acceptable experimental design to test a hypothesis)

.

- C - Control. It is essential to make sure that you can regulate and correct any variances that may avoid expensive flaws and quality loss.

2.3 LEAN MANUFACTURING

Lean Production was formulated by Taiichi Ohno, a Japanese engineer, he saw the need to create a better method of production that will give rise to efficiency and benefit the organization, also make them competitive in the western world (Berggren, 1993).

Management of lean is a good approach which includes strategic and measures of a system, when wholly considered, can lead to improvement, especially in the competitor's market, of particular focus are: product development, after sale service and supply chain. (Warnecke and Hüser, 1995). Operations using lean is also described primarily on determinants, tools and practices applied are considered, so as taken actions and alternation made to improve performance in an organization. Lean manufacturing has principles which focus on employees, the customers and minimizing waste, this supports Six Sigma's methodology of DMAIC (Shanley, 2017).

2.3.1 Elements of lean

Lean production has been divided by some researchers and authors into six or seven components. However, diverse authors have come up with their different elements;

Awaritoma (2010) identified seven wastes, while Cavallini (2008) identified eight possible wastes. Suffice to say, there has been different perspectives on types of wastes, these wastes are; Overproduction, waiting time, motion, over processing, transportation, defects and over processing, the eight-waste identified is Non utilised talent.

Intuitive approach, wastes elimination, less resources and speed were identified as the three objectives of Lean Manufacturing by Mezouari *et al*, (2013) which are used to resolve problems by using the following tools; Just in time, Value Stream Mapping, work methods standardization, value analysis and Kaizen.

Other researchers have mentioned attainable goals of Lean Manufacturing which are; reduction of cycle times, reduction of inventories, customer requirements that helps to create an improved rise output value through increased response time for customers and the reduction or elimination of non-value addition actions, benchmark output flexibility. (Desale and Deodhar, 2014). Figure 1 below shows the tools associated with lean manufacturing.

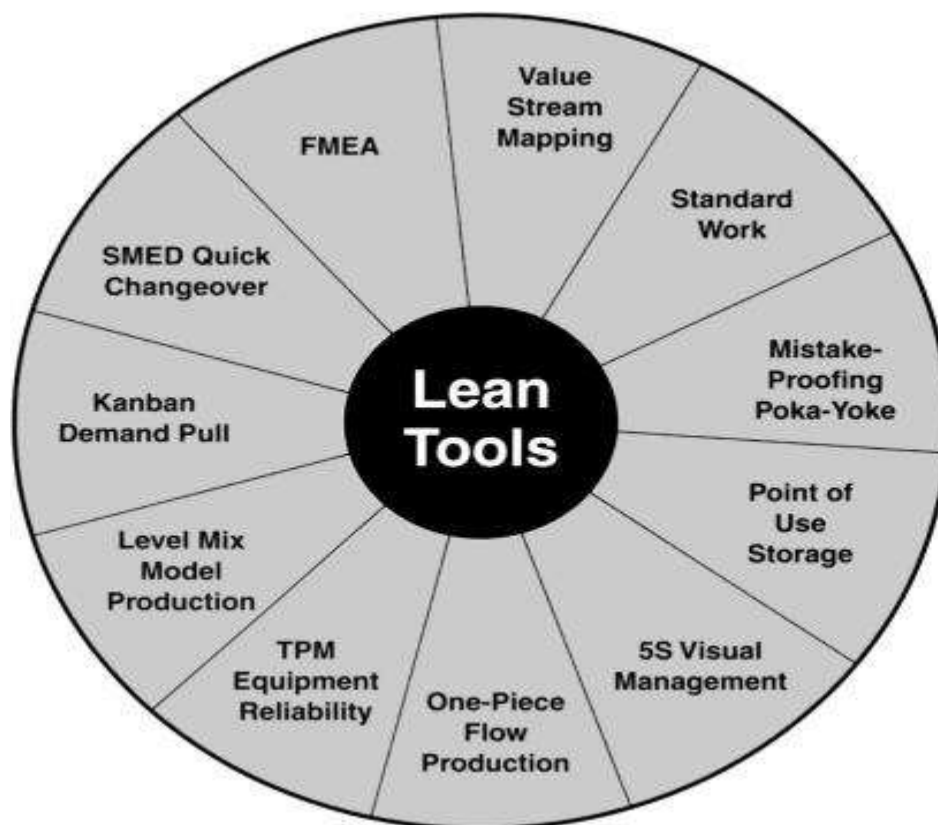


Figure 1: Lean manufacturing tools (George, 2005)

2.4 LEAN SIX SIGMA METHODOLOGY

The concept LSS began in 1997, the British multinational defense, security and aerospace company experimented the use of Lean manufacturing alongside Six Sigma (Rusko and Kralikova, 2011)

LSS is a methodology that can be used together for improvement of process and waste elimination, in high performing organizations, lean six sigma tools are implemented (Spector, 2006). Snee (2010) defines LSS as a properly based concept method to expand effective leadership, enhance performance and keep customer satisfaction, collectively using lean and six sigma eradicates the negative effect of each method.

Using tools of Lean production and Six sigma, tools like DMAIC are implemented alongside DMADV to attain better results. LSS is usually implemented through champions, masters, black and green belts respectively (Laux, Johnson and Cada, 2015)

Whether together or independently, Lean and Six Sigma can be used either ways. To improve business processes, manufacturing efficiency of design and intellectual property while reducing costs, lots of companies through different industries now adopt the implementation of Lean and Six Sigma to ensure the reduction of wastes, improve processes and innovation and can be applied in the pharmaceutical industry (Noori and Latifi, 2018).

2.4.1 Elements of LSS

Certain authors and researchers did not agree on LSS elements. Such authors will include (Subramaniyam *et al.*, 2011) who argued that there are five elements of LSS which includes; reduction of poor design, faster time to market, reduction in material cost, over design reduction and product development cost reduction. Meanwhile, seven types of wastes that could possibly be faced in a process of production were introduced by (Berty, 2011) as motion, over waiting, over production, inventory being over processed, transport when not needed, over processing of bad products and fixing defects. The business effects

of sustainable development's relationship with six sigma and lean production was studied by some authors like Clegg (2007) who found out through his study that a good relationship between socio-economic factors and six sigma could lead to Six Sigma sustainability. Concluding, Krambia-Kapardis and Loannou (2011) postulated that through the use of the tools from Lean Six Sigma, quality processes can be improved upon and save resources.

2.5 TOOLS OF LSS

- 5S: By improving the cleaning efficiency, this instrument ensures continuous improvement. 5S measures are to sort (to eliminate unnecessary products), to shine (to maintain the workplace clean), to set in order (to maintain everything in location), to standardize and to maintain (to ensure continuity). Standardized work to eliminate the first line supervisors ' unnecessary stock (Beger, 1997).
- Bottle neck analysis: The assessment of the bottle neck relates to the slowest portion of a process. They determine a process's largest by putting rate. This assessment introduces critical problems to the production of processes that hinder light. If it is possible to reduce the bottle neck process, the throughput and ability will improve (Colin, 2017).
- Value Stream Mapping (VSM) is a visual representation of the entire production process with the aim of eliminating all non-value-added activities, emphasizing value-added process activities and identifying waste.
- JIT: Just in time, using the necessary amount, the time frame required and ensuring the highest product quality for the client to function quicker (Plenert, 1997)

- FMEA: In the early phases of any item or process, Failure Modes and Effects Analysis (FMEA) enables companies identify and eliminate weak points. Developed in the 1950s, FMEA is used to examine parts, assemblies and subsystems to identify modes of failure and their causes and impacts. Lean Six Sigma practitioners use FMEA to improve the quality of their processes, services, and products by detecting barriers before they occur (DEAR Cloud Inventory Management, 2019)
- The 5 Why's: The 5 Why s is an instrument used by organizations to determine the root cause of issues. It is frequently implemented in DMAIC as part of the analysis stage. The problem is written down and why is asked repeatedly till the root cause is found (Gangidi, 2019)
- Continues flow; this simple implies that manufacturing does not stop moving once it has started. The entire production system component is examined waste such as waiting moment, downtime of machinery, removal of defects. And the procedures left is synchronized, streamlined and standardized (Siegert et al., 2017).
- Kaizen (Continues Improvement) Kaizen is a Japanese word which means improvement that is continued. This is an important tool in lean (Beger,1997). Kaizen or "Continuous enhancement" is intended to involve and train all staff in the operational phase and to coach them in their duties.
- Kanban (Pull System): it sets out all the present phase data and which sections are required for the next phase in order to react rapidly to modifications in the method to improve coordination. (Colin, 2017).
- KPIs (Key Performance Indicators): KPIs are measurements of how efficiently a company achieves main business goals. By identifying main process inputs that generate process outputs, they are leading indicators chosen. They are aligned with

strategic goals and used to monitor and monitor the efficiency of the process. Correctly chosen KPIs make it possible to expose waste drivers. They are used to motivate employees so they can drive result

2.6 LSS IN PHARMACEUTICAL INDUSTRY

Today, pharmaceutical firms face challenging duties such as adjusting to volatile and troubled market at a vital stage or turning point in the economy. In addition, they aim to satisfy their users ' requirements in keeping their health. However, it is very difficult to balance the desire to reduce costs on the one hand and ground-breaking design on the other. For instance, when it comes to fusion of Pharmaceutical companies, the aim is to eliminate cost.

The method of LSS reduces cost and encourages research development pharmaceutical and medical device manufacturers are making use of LSS principle to improve operational efficiency and quality, while facilitating compliance (Shaked, 2015).

The first step in accepting the Lean Six Sigma is to understand the need for change irrespective of its improvement quality. The true cost of manufacturing becomes visible when the non-value-added activities is being considered (Lertwattanapongchai and William, 2014)

LSS brings about reduced work in stock inventory, reduced waste, capital and resources used leading to better production cycle.

The success of the application of LSS in the pharmaceutical industry has prompted most companies to properly affect its use in the reduction of production wastes and waiting time, invariably improving all round quality in laboratories, communication with customers and production (Reoskar and Pohekar, 2013).

Economic crises can give rise to an unstable and turbulent market that can impact heavily on pharmaceutical companies and force an adaptive strategy on them by aiming to meet the demand of their customers. Through the reduction of cycle times and internal costs,

they try to meet all requirements, requests through the provision of high-quality delivery to consumers through innovation.

Striking a balance on the need for cost reduction and competitively applying innovative design is quite rigorous to achieve. The cut off of research and design departments help to reduce costs in the merging of pharmaceutical companies.

While allowing devotions, Katarina and Vojislav (2010) asserted that as a way of having a significant improvement, pharmaceutical and medical devices companies were now applying LSS ideologies for operational excellence and efficacy.

According to Jiju (2015), he highlighted that are certain restrictions that could possibly arise, especially from non-availability of data where it is most needed and could give rise to frustrations if only a small part is applied at the end to a solution that are expensive and data driven. A lot of consulting firms are said to be overselling, even when it is apparent that they do not have a full grasp of the systems and tools of the lean six sigma blueprint after claiming a false or overstated expertise to clients.

In the last few years, a few pharmaceutical companies started adapting Six Sigma with the aim of reducing cycle, time and cost. The process of identifying and authentication of a supplier of a packaging material usually takes 12 months because of the very complicated process involved. Using the LSS, methodology, GSK were able to streamline, the process and were able to reduce the cycle time from twelve to five months and realized saving that were significant (GlaxoSmithKline, 2004). Eli Lilly, Johnson & Johnson and Novartis are examples of pharmaceutical firms that have implemented Six Sigma and lean methodology (Stuckrath 2006).

Gray and Anantamula (2009) stated the following as key strategies suggested to launch a Six Sigma effort within the Pharmaceutical Industry.

- Start to always alter the tradition of conducting clinical trials by campaigning to implement the necessary inclusion of an introductory step by using six sigma with a dedication from top down management.

- Aim on the wholeness of technology and work flow improvement in meeting challenges and expand new commercial undertaking that risk about a promising profit
- Provides a study strategy tested for the qualitative assessment of the importance of clinical growth and process improvement strategies, extremely integrated and process improvement strategies, extremely interrelated integration with powerful economic results (Deepak et al, 2010)

Recently, comparing Lean Six Sigma to other principles such as CGMP in Pharmaceutical industries, the following observations were made

AREA	LSS	cGMP
Objectives	Reduce wastes Create value	Ensure product effectiveness Prevent harm
Focus	Value stream	Product development manufacturing quality assurance
Approach to manufacturing	Quality balanced with productivity	Quality first
Improvement	Continuous and simultaneous	Regulated and prudent
Typical goals	Reduce cost improve quality, Reduce cycle time, Reduce inventory, improve delivery.	Follow validated process, Prevent deviation
Typical tools	Value stream mapping' Kaizen' Improvement Error proofing moving to pull simple flow training quality function development	Documentation, Personal qualifications training, Cleanliness Qualification Complaint review Audits.

Table 1 Comparison of LSS and GMP in Pharmaceutical environment (Katarina and Vojislav 2006).

From the table above, the study showed that cGMP and Lean overlap with a shared manufacturing environment and can both be used in a manufacturing setting. The dual goal of Lean is to reduce or eliminate waste, while creating value; this differs from cGMP's goal, which is to ensure that a safe and effective medicine is produced at all levels of control.

2.7 IMPLEMENTATION OF LSS

Schroeder et al. (2008) documented that application of Six Sigma and Lean is based on appointment, leadership engagement, resources, communications, initiatives, disciplines and implications.

Furterer, (2004) Charted the Lean Six Sigma execution variables based on the parts of its structure. Six Sigma is the practice of continuously improving minimum defects by defining the level of measurement, analysis, optimization and control (DMAIC) developed through the Six Sigma design based on a robust design that meets customer requirements.

These comparisons indicate that LSS is a fresh approach to public order's fundamental productivity and proper implantation leads to success (Zhang & Xu, 2008). The findings of this research done by Alsmadi, Lehaney and Khan (2012) represents the impacts of Six Sigma's success factors, true case study in manufacturing and service organizations and stated that reasons for small application of Six Sigma led from the use of only classic statistical instruments, whereas sophisticated techniques and methods are used less frequently.

Successful implementation of LSS has to include committed leadership (Carleysmith et al., 2009), Organizational Culture that is quality driven (Koning et al., 2008), training (Delgado et al., 2010), teamwork, and Technical supportive systems (Psychogios & Tsironis, 2012).

Study by Delgado et al., (20110) conducted on Slovenian manufacturing, focusing on prevalent obstacles, difficulties and severe Six Sigma application achievement problems. The factors were described on the basis of Six Sigma literature. The most significant considerations for the achievement of Six Sigma application are "Six Sigma" and "Infrastructure," followed by "Cultural Change,

2.8 FACILITATORS OF IMPLEMENTING LSS

While globalism has opened more markets hitherto unimagined, its associated global competition alongside scarce resources, have driven companies to have effective, precise, and streamlined production processes to remain competitive (Eirin et al., 2016). To this end, industries, have embraced LSS which has been noted to help eliminate waste and improve efficiency.

Despite its wide acceptance by key industry players, the implementation of Six Sigma and Lean Manufacturing has been noted to be problematic by scholars (Denton and Hodgson, 1997; Jeyaraman and Teo 2010) thus, the need for a careful study of the factors that mitigate or hinder its successful implementation. It is in line with the above, that this section seeks to explore findings on the barriers and facilitators to LSS implementation. The term facilitators as used here refer to those factors that aid LSS implementation. Some of the factors discussed here are:

- Management Commitment
- Adaptability to change
- Training
- Proper Use of methods and tools

2.8.1 Management Commitment

Management commitment to LSS has been identified as one of the most important factors that influence LSS in organizations. Raghunath and Jayathirtha (2013) pointed that “Six Sigma is viewed by some organizations as just a passing management fad which only adds to cost without significant financial gains”. This makes its success difficult to accomplish.

Top management support for LSS is vital in two areas. First, the power and scope of Six Sigma requires a considerable obligation from the organization. This needs support from top executives to go beyond departmental barriers. Second, any sort of alteration in an organization will meet some resistance, either intentional or just by virtue of inertia. When upper management is behind that change, resistance can be countered and overcome (6sigma, 2013).

Eirin et al, (2016) in his study which interviewed top managers, middle managers and workers on their perception of Lean Implementation highlighted that it is essential to realize that all executives and not just the top management have to execute leadership. Good management will also affect the development of understanding and efficient abilities among the workforce

Qualitative Research conducted by Raghunath and Jayathirtha (2013) on implementation of Six Sigma in small and medium enterprise showed that the management team has to invest in skills and knowledge as not to hamper another critical success factor; knowledge about what is lean and the high performing level skills is needed, they also said It certainly works when a management gets actively engaged and promotes something. That's the big distinction between the other quality projects of Six Sigma. An organisation of Six Sigma is going to be proactive rather than reactive.

2.8.2 Adaptability to change

As mentioned above, any sort of alteration in an organization will meet some resistance, either intentional or just by virtue of disinterest. Thus, adaptability to change has been recognized as a great assert for LSS implementation. Brian, Mohamad and Chloe (2017) note that “Change is habitual, and individuals must be educated to make adjustments to remain afloat. If not, they may lose relevance during continuous change”. Hence, the ability for employees to adapt to change and not feel threatened by LSS is important to its success.

2.8.3 Training

The quality of training is vital to LSS implementation in any organization. For the set goals of an organization to be achieved, employees must be trained as LSS professionals (Raghunath and Jayathirtha, 2013). When employees are qualified either as: Champion, Black Belt, Green Belt, Yellow Belt, Master Black Belt, and Sponsor, it facilitates the easy implementation of the program.

Not many people understand LSS. To this end, there is the false notion that LSS is too complex; this can be addressed by training employees to enable them to have a better understanding of the program. Abdullah and Patrick (2016) affirm to this view when they listed training as a key factor to the successful implementation of LSS in any organization.

2.8.4 Proper Use of methods and tools

Nethland, (2015) stated that the use of instruments of procedures makes it efficient and essential to disseminate lean values, it also improves the chance of predictable execution, in his study he listed some lean tools such as, 5s, Kaban, JIT, value stream mapping, problem solving and total production maintenance,

The isolated use of tools and practices is insufficient with regards to disseminating lean principles

For instance, value stream mapping generally emphasizes the technical elements without taking into account the barrier management mechanism (Marodin and Saurin, 2015).

In addition to the strict technical elements of implementing instruments and procedures, human and organizational factors must be seen and be related to the technical aspects.

2.9 BARRIERS OF LSS IMPLEMENTATION

Barriers here refer to those factors that slow down or hinder the implementation process of LSS. While there is no universal agreement by scholars as to the barriers of LSS, we

have identified quite a few worth discussing in this study. These include but not limited to:

- Lack of Finance
- Management Apathy
- Internal resistance
- Company Culture and
- Poor Training

2.9.1 Lack of Finance

Crucial to the success of LSS is finance. Writing on its importance, Raghunath and Jayathirtha (2013) on their work on the *Barriers for implementation of Six Sigma by Small and Medium Enterprises* noted that “A Six Sigma project would consume a lot of company resources like financial resources, human resources, time, etc”. The inability to meet up the financial obligation of LSS has led to a poor interpretation of the LSS project in its implementation stage.

While writing on this, Stephen, Ann, and Kevin (2009) noted that the barriers to LSS in their study “were mitigated by strong sponsorship”. Similarly, Jeyaraman and Teo (2010) argued that:

“The LSS needs some significant investment of company in developing resources, training materials, statistical software licensing purchase, seeking consultation advice, reward and recognition system and others in order to cultivate and sustain the culture. Therefore, in order to facilitate a successful LSS implementation, company financial capability is a vital factor in increasing the likelihood of LSS implementation success of an organization”.

The implication of the above is that, were companies are unable to meet the financial obligations of LSS, critical areas such as good training needed for the success of the program will collapse. To this end, lack of finance has been identified as a barrier to LSS implementation.

2.9.2 Management Apathy

Management apathy refers to the lack of interest/commitment by top management to LSS. Eirin, Jonas, Inger, and Silje (2016) in their study of Barriers to lean implementation: perceptions of top managers, middle managers and workers noted that “Management commitment and leadership is regularly highlighted as the most pertinent CSF in driving a lean implementation process. Hence without a visible and active support from management, lean implementation is unlikely to succeed”. To this end, they argued that the management team must understand the level of effort needed, time and manpower needed for LSS implementation to be successful.

In agreement with the above line of thought, Pande et al., (2000) in Jeyaraman and Teo (2010) extensively argued that “without the continuous support and commitment of top management, the true importance of LSS will be in doubt and the energy behind it will be weakened”. Similarly, Stephen, Ann, and Kevin (2009) in their study found out that top management who were not convinced of the benefit of LSS sabotaged the process and thus, hindered its implementation.

2.9.3 Internal Resistance

One of the biggest challenges of LSS implementation identified by scholars is internal resistance to change. Raghunath and Jayathirtha (2013) noted that resistance and skepticism are common occurrence to change in any organization. LSS encounters this because it tries to eliminate waste and improve efficiency by applying changes to the traditional ways of doing things. The knowledge gap that exists between the initiation and implementation process is what leads to resistance. Due to lack of understanding of what LSS represent, employees feel threatened by it.

Following from the above, Richard (2019) noted that “A critical element of any successful Six Sigma plan is to surmount resistance to change. The rationale for this assertion is that: Without user approval, any process improvement is destined to be unsuccessful. Consequently, proper anticipation and understanding the approaches to various resistance tactics is essential to success”. To this end, Kumar and Kaushish (2014) highlighted the need for organizations to have a change management plan to remedy this malady.

2.9.4 Company Culture

Organizational culture has been identified as one of the greatest impediments to LSS implementation. Abdullah and Patrick (2016: 40) citing Pooyan, et al. (2014), notes that “organization’s culture is the most important factor that affects the implementation of LSS”. To this end, they stressed the importance of an appropriate lean culture to the pace of the growth and the firm’s competitiveness.

Emphasizing the importance of organizational culture to the success of LSS, Kumar and Kaushish (2014) stressed that dealing with the challenges and issues that are easy to correct and claiming that the six sigma methods is a big success is simply self-deceiving as the more important concern lies in changing the managerial culture that does not put quality into planning.

Some of the organizational culture that has been identified to impede on LSS implementation are “employee involvement, creativity, problem solving processes, decentralization, control and standardization, efficiency, productivity and continuous improvement,” (Pakdil and Leonard, 2015b, cited in Abdullah and Patrick, 2016).

2.9.5 Poor Training

It is a self-destructive approach to pay less attention to training in the implementation of LSS. This is key to the success or failure of the project as it prepares employees and management alike for the task ahead. Kumar and Kaushish (2014) found out that “the selection of less-capable employees for Black Belt assignments was associated with challenges to six sigma projects”.

In a similar study, Raghunath and Jayathirtha (2013) noted poor training and coaching to be the greatest barrier to implementation of Six Sigma in SMEs to date. The issue of poor training is linked to poor understanding/interpretations of the demands of LSS. Authors such as (Raghunath and Jayathirtha, 2013; and Kumar and Kaushish, 2014) have stressed on the importance of putting considerable resources and time on training to get the best out of LSS.

2.10 CONCEPTUAL FRAMEWORK

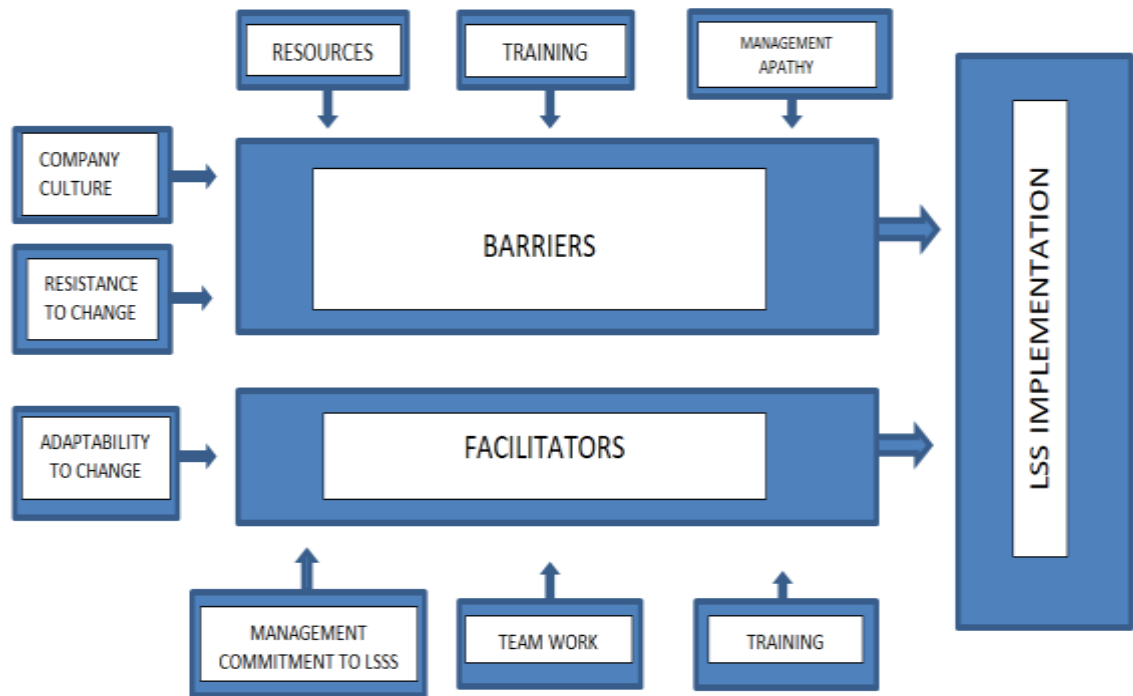


Figure 2: Conceptual framework for Barriers and Facilitators to LSS in Irish Pharmaceutical Companies

This section is on the conceptual framework of the study. In the cause and effect relationship, we deal with two variables, the dependent and independent (Fisher, 2010). To this end, the connection between the independent and dependent variables will be established here. The independent variables in this study are the barriers and facilitators while the dependent variable is the implementation process. Hence, the framework of how the barriers and facilitators influence the implementation of LSS will be established.

2.10.1 Barriers of LSS

Barriers refer to the factors that hinder the successful implementation of LSS in Irish Pharmaceutical companies. They include:

- Resources
- Training
- Management Apathy
- Resistance to Change
- Company Culture

Resources

Resources refer to the human and financial materials needed for the execution of LSS. The implementation of LSS is likely to consume a lot of human and financial resources. Thus, the shortage of any of these is likely to have a negative impact on the implementation process. This is due to the fact that while human resources are needed to run the program, financial resources are required to prepare the human resources for LSS implementation.

Training

Training refers to the process of preparing the employees for LSS through the act of teaching the basic skills required for its success. This is connected to the first point as finance is needed for adequate preparation for LSS implementation. When training is done poorly by unqualified trainers, employees will lack the necessary skills required to implement LSS successfully.

Management Apathy

Management apathy is the disinterest to LSS shown by top executives of the organization. LSS depends on the commitment of everybody to work as it requires a top to down approach. Hence, when top management who are supposed to its driving force are disinterested, it hinders the implementation process. Pande et al., (2000) in Jeyaraman and Teo (2010) extensively argued that “without the continuous support and commitment of top management, the true importance of LSS will be in doubt and the energy behind it will be weakened”.

Resistance to Change

Resistance to change refers to the unwillingness of employees to accept new ideas and innovations different from the traditional ways of doing things. LSS is innovative and its success depends on the innovations to improve efficiency and eliminate waste that it constantly brings. Richard (2019) noted that “A critical element of any successful Six Sigma plan is to surmount resistance to change. The rationale for this assertion is that: Without user approval, any process improvement is destined to be unsuccessful.

Company Culture

Company culture refers to the way and manner things are done in the organization. Some company culture is too rigid, and this kind of culture is anti LSS which depends on flexibility and pro-activeness to thrive. Kumar and Kaushish (2014) stressed that dealing with the challenges and issues that are easy to correct and claiming that the six sigma methods is a big success is simply self-deceiving as the more important concern lies in changing the managerial culture that does not put quality into planning

2.10.2 Facilitators of LSS

Facilitators refer to the factors that make the implementation of LSS easy. The facilitators of LSS include:

- Management Commitment to LSS
- Adaptability to Change
- Team Work
- Training

Management Commitment to LSS

Management commitment is defined as the dedication or interest top executives show towards the success of LSS. As stated earlier in this section, LSS is a top to down thing. Thus, no matter how committed the employees are, if the top executives are not dedicated to its success, it will be difficult for it to succeed. Consequently, LSS needs support from top executives to go beyond departmental barriers. To this end, when the commitment from top management is there, implementing LSS becomes easy.

Adaptability to Change

Adaptability to change here refers to how easy it is for employees to accept change. LSS is innovation, and its success depends on its acceptance by not just the employees, but

also by the top management. To this end, adaptability to change helps to facilitate the implementation of LSS.

Team Work

Team work refers to the collaborative effort of employees and top management to the implementation of LSS. This is related to management commitment to LSS, but a little bit wider in scope. When both the employees and top executives are willing to work as a team, information is shared amongst the different teams and as a result of this, common huddles to LSS implementation are defeated. Hence, as oppose to individualism, team work is a facilitator of the LSS.

Training

Training is the act of transferring knowledge from one individual to the other or the act of acquiring new skills through the process of learning. Without training, the implementation of LSS is simply not possible. Consequently, good training of both employees and top executives facilitates LSS implementation. When employees are qualified either as: Champion, Black Belt, Green Belt, Yellow Belt, Master Black Belt, and Sponsor, it facilitates the easy implementation of the program.

CHAPTER THREE

3. METHODS

3.1 INTRODUCTION

This Chapter will explore the research philosophy and approach, research strategy, research design, collection of data, research ethics and data analysis method. Ghauri & Gronhaug (2010) defined Research as a procedure people venture in a systematic way in order to get more knowledge and awareness, and to discover new things

In his book (Kothari, 2008) Solving problem systematically is termed Research Methodology, it is also known as a science of examining research and how it is scientifically done. He further explained that it is important for the researcher to know the methodology and research techniques, in addition, he explained that research methodology should not just be about the research method which includes procedures used to gather data and analyse the data, but should also include justification for the selected methodology, why a particular method is used for the research and why others are not used, also the method used for data collection, the type of data, technique for analysing the data as methodology has many dimensions and is broader than methods and these are the various steps usually utilized by researchers to examine his or her research problem.

This chapter will include and explain the methodology used in organizing this research. The chapter will describe how research data was collected to get answers to the research questions, the design of the research, the materials and methods used for data collection, analysis of the data, justification for the selected methodology, data analysis type and ethical issues considered while conducting the research.

3.2 RESEARCH PHILOSOPHY AND OVERALL APPROACH

Our decisions are affected by our beliefs and assumptions, this will have a major effect on how a researcher selects and decides the methods used during course of the research (Saunders, et al., 2016). Research Philosophy is all about knowledge development in a particular field through assumptions and belief, it is the belief on how data should be acquired, three types of assumption are looked into, they are; Ontology, epistemology and axiology (Saunders, et al., 2016). Ontology deals with the researchers' view of nature of reality, this determines and shapes how the researcher sees objects of research (Saunders, et al., 2016). Researchers view and Assumptions about knowledge acceptable during the research is Epistemology, (Burrell and Morgan, 1979). Axiology refers how the researcher deals with their value and that of participants in the research study.

Research philosophy clarification is the beginning point for the decision of research methods. According to Saunders, et al.,(2016) there are five major philosophies in Management and business research, they include; Pragmatism, Positivism, Interpretivisms, Critical realism and Postmodernism.

Research Philosophy for this thesis is Interpretivisms.

To A pragmatist not one single view of how you research the world will give you the total answer (Kelemen and Rumens, 2008). This calls for the use of mixed methods (Saunders, et al., 2016). This thesis involves a subjective perspective and utilizes one qualitative technique; this is in contrast to pragmatism.

The Positivist Philosophy was not selected by the researcher because this thesis involves qualitative method and the perception of the human subjects influences the data. Gill & Johnson (2010) said Positivist emphasises on factual scientific approach to get conclusion, and the information derived is not influenced by human perception and they use quantitative method.

Critical Realism philosophy emphasises on clarifying experiences and what is visible, to a Critical realist, acceptable knowledge is historical; they try to be very objective in their

research (Saunders, et al., 2016). This research is subjective which is in contrast to Critical realism

Postmodernism is all about the in-depth investigations to the general way of thoughts and be a voice to views that have been belittled and excluded (Calas and Smircich, 1997). To a Postmodernist, some realities and knowledge are suppressed, different data type are used to get result as the researcher is open to data deconstruction (Saunders, et al., 2016). This philosophy was not selected because this research will be using one data type, which is qualitative.

Interpretivism from a subjective perspective criticizes Positivism from a subjective point of view; they maintain that physical occurrence is different from humans, because meanings are conceived. To an interpretivist, reality has different meanings and understanding, and it is complex, Axiological, their values plays a major role in the research as they are subjective to the research and they accept an empathetic stand while they include their participants interpretation in the research. Epistemologically, their core accepted knowledge is on perceptions, explanation and stories, with a contribution of historical facts, the aim of a research conducted by an interpretivist is to formulate better understanding of the world (Saunders, et al., 2016). Most used method for an interpretivist is qualitative with deep investigation and more of small sample, researchers with interpretivist philosophy work inductively, they analyse their data and identify themes in the data.

The research philosophy implemented in this research is Interpretivism, which is a Subjective. The research will focus on experiences of the participants and their personal interpretation. The research topic will be evaluated using opinion of individuals based on their experiences and understanding of the barriers and facilitators of implemented LSS in their organization, the research will subjective to ideals and experiences of participants, hence the use of interview which is qualitative to get the perspective of different group of people within the pharmaceutical industry. Interpretivism philosophy will aid this research meet its aims and objectives.

3.2.1 Research Approach

The approach that will be taken for this research is Inductive thematic approach, as the result from this research will be the theory formulation

The research would start by interviewing a sample of employees in Pharmaceutical Companies in Ireland about their perspective on the barriers and facilitators of LSS the data collected will be analysed, themes will be created and the result of the analysis of the data will be used to formulate a theory.

The inductive method utilizes research questions to reduce or deepen the study's scope.

According to Ketokivi and Mantere (2010), there are three approaches to theory development, which are Inductive, Deductive and Abductive approaches.

Deductive approach is usually theory driven and from existing literatures, it starts from general to specific and data collected is simply used to evaluate and test the hypothesis which is similar to already existing theories

Inductive approach on the other hand begins with data collection which will be used to explore and evaluate an experience, identify themes, analyse and clarify patterns and create new theories or modifies theories which already exist; a conceptual framework is also created in this approach. Abductive approach is similar to inductive, data collected is used to test theories and afterwards test through more collection of data.

3.3 RESEARCH DESIGN

The way research questions and objectives are formulated into a research project is termed Research design, it is a total plan of how questions asked during the research will be answered, it entails data sources, how to collect data and analyse the data, constraints and ethical issues researcher might face will be discussed . The design is influenced by the choice of research philosophy and approach (Saunders, et al., 2016). According to Kothari (2008), a research design is the organization of conditions for data collection and analysis in a way that combines economy in procedure and importance to the research

This study employed an inductive qualitative research design. The most popular type of research concepts used is quantitative and qualitative. According to Creswell (1994) quantitative is often used in collecting data that involves questionnaire or statistics, it appears in number form and measurements which are specific. In contrast qualitative research often involves, techniques like interview, observations, and focus groups performed in small and specific sample and it is usually linked to interpretive philosophy (Denzin and Lincoln 2011).

A qualitative design was chosen to derive in-depth knowledge and insight into the view point of the participants concerning the facilitators and barriers of LSS that they have experienced in their organization and it is the best approach for understanding and exploring what individuals ascribe as human problem.

Furthermore, a study that includes perspective of employees' calls for a qualitative method to get a better understanding through the experiences, reports and interpretation of participants, result will be achieved via interview. Most qualitative research begins with Inductive approach to develop theories, which is the approach used by the researcher. Quantitative design was not selected because it is used mainly for testing theories which are objective and it involves control for alternative explanations, this method will no help this research meet its objective as stated in Chapter 1.4.

The nature of data collected during a research will either be descriptive, explanatory, evaluative exploratory or a combination of either of them (Saunders, et al., 2016).

Data collected during this research will demonstrate exploratory research question.

According to Saunders et al. (2016) Exploratory study ask questions to gain knowledge about a research area and to learn about happenings in the topic area, questions like How and why are asked, exploratory research is conducted via interviews or focus group.

Exploratory research selected and used by the researcher will involve use of interview by interviewing employees of pharmaceutical companies, which are knowledgeable and expert in the LSS which will give the research a better understanding of the barriers and facilitators to implementation of LSS in Irish Pharmaceutical Companies.

Descriptive is used to get accuracy and asks questions like ‘When’, ‘Who’, ‘How’ or ‘What’, according to Saunders et al. (2016), these questions give description of situations. Explanatory research focuses on problems and explaining relationships between different variables, for data collection, Evaluative research questions on the other hand aims to find the effectiveness of existing facts.

3.4 RESEARCH STRATEGY

Strategy for research is a plan that shows how the researcher will answer his/her research questions (Denzin and Lincoln 2011). Preference of research strategy will be guided via the research objectives and questions; it is also linked to the selected philosophy.

Saunders *et al.* (2016) highlighted the different types of strategy for research and they include: Case study, experimental research, grounded theory, action research and survey. Some of these strategies are linked to either quantitative or qualitative research.

Case study according to Yin (2014) is an in-depth study of an experience within its actual environment leading to theory development; this research may be of an organisation, a group, a person or a process. Case study can generate knowledge and it is used in description of events in the day to day context as they happen. This research strategy is used mostly by Interpretivist, also positivist, data collection method for Case study can be focus groups, interview, questionnaires, reflection and different form of observation (Saunders, et al., 2016). Yin (2003) said a case study research strategy can involve multiple cases.

Although there are different types of research strategy, the strategy selected by the researcher is Case study; it is mainly linked with interpretivist philosophy and inductive research, which the researcher implemented for this research. According to Saunders et al. (2016), Case study strategy can generate insight from research and develop relevant understanding into the study of a phenomenon, which could be a company, a process or an event; it is usually in a real-life context.

The research topic examines barriers and facilitators of Implementation of LSS in Irish Pharmaceutical companies, this is the best strategy for the research topic area and it gathers in depth knowledge of current happenings and past situations and relevant personnel are considered and data will be collected via interview. Different employees of different Pharmaceutical companies will give their personnel experience and perspective of the research topic as multi case study will be incorporated,

3.4.1 Recruitment

Recruitment took place over 4 weeks from 20 July to 10 August 2019. In this research, the researcher used her contact at different Pharmaceutical Companies selected for the study to distribute email to the targeted participants. Reminder emails were sent 4 days after as a follow up procedure. 15 employees from different Pharmaceutical companies in Ireland were invited to participate in the interview, 5 responded and agreed, 1 responded and did not agree, 9 did not respond. The researcher sent messages and emails to participants showing details of the research topic as seen in appendix B

3.4.2 Sampling

The aim of Sampling is to choose from the population, a subset of individuals to get findings that represents the entire population's characteristics (Fisher, 2007). There are different types of non-probability sampling, which includes, quota, convenience, purposive and snowball sampling (Fisher, 2007). Purposive sampling was used for this research. While selecting the unit to be studied, purposive sampling relies on the researcher's judgement and the main goal is to focus on a unique population of interest that can best answer the research question.

For this research, Pharmaceutical Manufacturing organizations was selected and a purposive sample ($n = 5$) of industry employee in Lean Six Sigma utilization were selected to participate in the interview. Sample of different staff in pharmaceutical industries were

selected, approximately 5 People in different Pharmaceutical companies in Ireland and invited to participate, they were accessed by sending mails to their LinkedIn profile. The Sample of 5 Participants was comprised of 2 male and 3 females, 3 stated that they had trainings and are belt holders in LSS, 2 were managers in their companies.

3.4.3 Setting

Telephone or face to face interviews were conducted by the researcher depending on the participant's preference to examine the research topic from July 12 to August 10, 2019. Face to face interview was conducted in the participant's work place in a quiet and private room.

3.4.4 Role of the Researcher

This researcher adopted the role of an external researcher, according to Saunders et al. (2016) this role is ideal for a full-time student. The researcher identified Pharmaceutical organization as the setting for the research and negotiated access to employees in the organization. The method and data tool selected by the researcher is qualitative interview, for this research, a question guide was created to aid the interview as seen in appendix A. The topic guide was developed to direct the research in the right way, this was scrutinized and approved by the supervisor.

The researcher used the following strategies to gain access and conduct the research; these strategies were mapped out by Saunders et al. (2016)

- The researcher ensured he/she was familiar with the Pharmaceutical Companies before building contact
- The researcher made a list of employees to invite for the interview.
- A clear account for the reason for the research was made and the access type needed, this was drafted in a Participant letter as seen in Appendix B.
- No disagreement during the interview.
- All points and opinions of participant were noted.

3.4.5 Ethical Issues

Ethics in research highlights wrong or right actions. Research participants should not be subjected to harm, psychologically, financially or socially, also to risk of pain (Kovarikova, 2014). During the research, members aged over 18 years were included in the investigation.

Participants were briefed on what the research is all about before the interview appointment. A consent form was sent to all participant before the interview, which was signed by the researcher and participant, see appendix C for consent form. Participants selected for the researches were assured that their identity together with that of their companies will not be made public and remain confidential. Participants were informed that their participation in the interview was voluntary and had the right to pull out of the interview if uncomfortable. Names of Pharmaceutical companies include in this research was not disclosed in the thesis this paper. Notes and recordings were collected during the interview after getting approval from participants. All participants were told that a copy of the result from the researcher can be shared with them and provided based on request.

3.4.6 Data Collection tool

Data collections commence after the research problem has been identified and there is a mapped-out research design, this data could be primary or secondary data (Kothari, 2008).

One of the most popular methods for getting qualitative data is through interview; it involves verbal stimuli and reply in verbal responses (Kothari, 2008). This method can be through telephone or personal interviews. As explained by Yin (2003), an interview can be defined as a conversation which is guided between a researcher and an informant; it can be structured, unstructured and semi-structured.

For this research, a semi-structured interview tool was developed to guide data collection through both face to face and telephone interview. The interviewer developed topic guide

that she wishes to cover during the interview, the guide gave room for consistency, ensuring the same topic was addressed and discussed by each participant. The semi-structured interview gave room for new issues to be talked about by the participants. The topic guide included open-ended questions, of which some were descriptive (Question 1: Please describe your role in your organization?), the other questions were exploratory (Question 5: What factors have facilitated the implementation of LSS in your company?) The participants picked dates, time and place which were favourable to them, interview length ranged from 12 to 32 min, which were audio recorded and transcribed prior to analysis of data.

3.5 DATA ANALYSIS

Barriers and facilitators of LSS were analysed using Inductive thematic analysis. Barriers were defined as obstacles that would prevent implementation of LSS (Eirin et al.,2016). Facilitators were described as supporting procedures for LSS implementation Interviews conducted were recorded via audio and transcribed, the transcribed interview were analysed and coded by the researcher using a known qualitative data analysis software NVivo. The data analysis used the phases of thematic analysis which includes; data familiarization, initial code generation, looking for, naming, describing, analysing and generating results (Clarke and Braun, 2016).

The transcript was properly read and re-read, as the researcher payed attention to barriers and facilitators of LSS, significant statements or themes were found. Themes found were organized in hierarchical order of three levels of data analysis. First level had text selected across the data set relating to barriers and facilitators associated with LSS implementation in Irish Pharmaceutical Companies. Next level had the subthemes, where codes sharing similar meaning were combined, the third level focused on the main barriers and facilitators of LSS implementation.

3.6 CONCLUSION

This chapter has presented the methodology used by the researcher to answer the research question of barriers and facilitators of LSS implementation in Irish Pharmaceutical Companies

This chapter has presented all the steps taken to achieve the completion of this project, in the next chapter there shall be presentation of data from findings.

CHAPTER FOUR

4. FINDINGS AND DISCUSSIONS

4.1 OVERVIEW

This section is dedicated to analysing the research data retrieved from the research interviews. The study adopted both the inductive and deductive approach to achieve its aim. To this end, a coding system was applied to the transcripts as seen in appendix D using constructivist thinking, and an inductive content analysis developed thereby allowing themes to emerge and thematic analysis was finally applied to analyse the data. The aim of this study was to identify the barriers and facilitators to the successful implementation of; Lean Six Sigma in Irish pharmaceutical companies. A cross-sectional analysis of the entire data was carried out and four key themes were identified and assigned to two categories: barriers/ facilitators. A cross sectional analysis was applied to filter the raw data and fetch the relevant themes for the study. This was done by observing

the patterns from respondent's responses, similar responses were then grouped together to form a theme. To this end, theme 1 (Training) was generated from question 2, and 3, theme 2 (Tools for implementation) was generated from question 2, and 4, theme 3 (Company Culture) was generated from question 5, 6 and 7. It is however worthy of mention that the themes overlapped each other thereby falling into both categories depending on certain variables. The themes which were analysed are;

- i. Training
- ii. Tools for Implementation and
- iii. Company Culture

4.1.1 Participant Characteristics

A broad range of production industries including medical devices, packaging and Pharmaceutical sector were targeted, of these, only two sectors have replied that understand the importance and purpose of this study, 3 from medical device, 2 from Pharmaceutical. A total of 5 responses were received out of the 15-invite sent, 4 responses from the larger manufacturing companies, while 1 from the SMEs. Table 2 shows a summary of the participants

Respondents	Gender	Qualification	Role in Company	Six Sigma Belt	Number of Years Spent in Company
Participant 1	Female	Materials Engineer	Materials Engineer	Yellow belt	Nine Months
Participant 2	Female	N/A	Operations Director	Yellow belt	Four years
Participant 3	Female	Engineer	Commissioning and	Black belt	Five Months

			Qualification Engineer		
Participant 4	Male	N/A	Lean Six Sigma site lead	Masters Black Belt	Eleven Months
Participant 5	Male	N/A	Production Line Technician	Yellow belt	Three years

Table 2 Bio Data of Participants

4.2 RESEARCH FINDINGS

4.2.1 Training

A critical analysis of our raw data revealed that one of the things that can either act as a barrier or facilitator to the successful implementation of the Lean Six Sigma is training. The business Dictionary defines training as “an organized activity aimed at imparting information and/or instructions to improve the recipient's performance or to help him or her attain a required level of knowledge or skill”. This factor depends on the combination of certain variables such as: experience of trainers, types of training, people involved in the training, finance and the method of training.

A participant said that if their company had qualified personals to execute the program then it becomes a facilitator. This position is revealed by Participant 4 who noted that the main thing is to “actually get the resources freed up to do the exercises” Thus, it becomes imperative for the trainer to prepare the minds of the employees and all those involved on the benefit of the project.

To buttress the importance of this Participant X who trains staff on LSS noted that he “makes them understand or try to make them understand the changes are to make their jobs easier, to get better results, it's not to get more work out of the market, push them harder, or to make them go faster, but to make their jobs more easier to perform”

Another critical area is the people involved in the training process. As one participant 4 puts it “if your management aren't involved, actively participating, it will fail, it will fail every single time Despite the above assertion, one thing is also imperative; the success of Lean Six Sigma also depends on the active involvement of all parties in the organization. This corresponds with the views of Participant 2 who noted that

“The responsibility is across everybody in the organization” To further buttress the importance of this, participant 5 noted that “it is a top to down approach; everyone is involved in the implementation”.

Similarly, Participant 1 upheld the general sentiment of team play as a facilitator when he asserted that “both managers and I suppose and other people like associates are very important in implementing the Lean Six Sigma, like everybody has to be involved, it’s part of the culture here”. This sentiment was further echoed by Participant 2 who stated that “It’s all levels, and it’s like from our associates, which would be our technicians or our operators who work on the process right the way up to senior managers. And so everybody is involved in our, I suppose our improvement programs”. Following from the above, we can deduce that team play facilitates the successful implementation of Lean Six Sigma.

Other areas that are not quite clear due to shortage of data are the level of influence an external or internal training has on the implementation of Lean Six Sigma. This is in lieu of the fact that a Participant X noted “where the official authorities were to train our own staff, the staffs is interested, interested in doing different tools that I'm aware of”. Also critical to the successful implementation of the Lean Six Sigma is the methods of training where questions like the program being compulsory or optional for employees arises. The above position was asserted based on the claims of participant X who replied to the question: Is the training for like every staff that comes in or for existing staff? With:

if you are interested, you can be part of the 5S team so that would be more of a hands on training where you actually go into the 5S, but we also do have read and understand training for you, where you get trained online, on how to use the tools. You would read or have different kind of quizzes and questions on the different tools that would help you to use them.

4.2.2 Tools for Implementation

Question 2 from the topic guide as seen in appendix A asked how is LSS implemented in your organization and the tools used, this led to the formulation of the second theme

As regards the impact of tools to the implementation of the Lean Six Sigma, the question revolves round what level of impact does using a single or multiple tool have on the implementation of the program? It is interesting to note that all of our five participants admitted to using multiple tools such as 5S or Kaizen. The question that arises from a situation like this is: does this have an effect on the overall implementation of the program?

Participant X stated that the kind of tools used in the implementation of the Lean Six Sigma. Participant 1 noted that "...our organization, there's a lot of training available for all the different tools of six sigma. So, we've got both internal training within the plant where we use to training tools such as 5S or Kaizen, things like that". Participant 2 also admitted that all or most of the tools have been implemented in their company.

4.2.3 Company Culture

Investopedia defines company culture as the beliefs and behaviours that determine how a company's employees and management interact and handle outside business transactions. An analysis of our data revealed that this is a major factor as to the successful implementation or failure of the Lean Six Sigma in the pharmaceutical industry as all 5 of our respondents affirms to this. While it has been established that the culture of a company is a great influencer to the Lean program, the question that we are left pondering is how?

To answer this question, our first respondent noted that "no matter how the customer or the management wants something to happen, if the associates or other people that are not managers don't want to do it, it's not going to happen. So, it's the company culture..." He went further to clarify what he meant by this when he added that "the culture here in my own organization, is that it's very, very focused on the six sigma and everybody's happy to work together to improve different processes using the tools of Lean Six Sigma. The

above is quite revealing, as it shows the importance of a proactive and flexible culture as a facilitator to the successful implementation of the Lean Six Sigma. What this means is that for the lean Six Sigma program to work in any organization, and then the top management and staffs must be very willing to give it their best shot.

In addition to the above, Participant 2 went a step further to note that it's not just the responsibility of your technicians, or the responsibility of your senior management.

“And, I suppose, what we have seen is where individuals take responsibility for deployment of Lean Six Sigma tool like, the implementation of our Kaizen and Gemba Walk. And, you know, and using our root cause analysis to investigate issues and problems. And I suppose, when actually people take responsibility, and to work and to deliver a particular element, and then you get the volume, as opposed to somebody directing you to users... I suppose, it's the culture within the organization. So, it's a culture with a mind-set for continuous improvement”

This position is affirmed by the findings of Antony (2008), who in a similar study noted that one of the major barriers experienced in the implementation of Lean Six Sigma in NHS in Scotland to be the current culture of the institute, whereby, not many staff members were willing to adopt change in order to introduce the Lean Six Sigma. The traditional bureaucratic systems of admitting patients and releasing them are not easy to abandon. Bureaucratic systems are found where processing of insurance of the patients is full of unnecessary steps that are costly to the institute (Anthony, 2008; Waweru, 2014). The above points to the fact that companies with a culture of unnecessary bureaucracy are more likely to fail in the application of Lean Six Sigma. In other words, the bottleneck culture of most big and small businesses has been identified here as a barrier to the implementation of the Lean Six Sigma. As one respondent puts it “what people do is, they go away so they don't get this process” (Participant 3, 2019). Thus, where people think that the job is too complex, they will tactically avoid it even if it leads to efficiency. In response to this problem, participant 4 notes that he makes the staffs understand that the Lean Six Sigma program is not there to push them harder, or to make them go faster, but to make their jobs easier to perform (Participant 4, 2019).

4.3 DISCUSSION OF FINDINGS

The need to eliminate wastage and improve efficiency in order to maximize profit while also meeting customer's satisfaction has made several businesses both large and medium to embrace the Lean Six Sigma model. The pharmaceutical companies are not left out on this developing trend. While there are abundance of literatures emphasizing the benefit in this approach, several factors have been identified that can either hinder or facilitate the successful implementation of the lean six sigma in a business. Using data drawn from five participants this study was able to identify Six themes for analysis that can either act as barriers or facilitators to the successful implementation of the Lean Six Sigma in pharmaceutical companies.

From the analysis of the key themes discussed in this chapter, five (5) barriers and (4) facilitators to the implementation of the Lean Six Sigma in pharmaceutical companies were identified. Under the barriers were factors such as: lack of finance, lack of qualified personals, management apathy, complex bureaucracy and resistance to change. While the facilitators are: application of multiple tools, team work, management commitment to Lean Six Sigma and adaptability to change.

4.3.1 Barriers

Barriers refer to factors hindering the successful implementation of the program. Those factors as identified in our study are discussed below.

➤ Lack of Finance

The findings of this study revealed a significant connection between shortage of funds and poor implementation of the Lean Six Sigma in companies. This connection arises from the fact that lack of finance greatly influences things such as quality of training, types of tools etc. all the participants in the study agreed that finance is a great factor when implementing the Lean Six Sigma program. This position is revealed by Participant 4 who noted that the main thing is to “actually get the resources freed up to do the exercises”

The prevailing position amongst the respondents revealed that the availability of funds aid the training of a large number of people and the deployment of multiple tools for

training. Using the logic of the relational outcomes of this kind of training and the corollary impacts it will have on the overall program, it is only logical to assume that where there is an absence of such funds to carry out that level of training, the result will be poor thereby presenting lack of funds as a barrier to the successful implementation of the Lean Six Sigma.

➤ **Training**

Since the successful implementation of Lean Six sigma depends highly on very experienced personals, the cost of training the required manpower for the successful implementation of the program can act as a hindrance. To this end, the importance of an experience instructor cannot be over stated. The reason for this assertion is hinged on the fact that Lean Six Sigma comes with the implementation of good changes to the traditional way of doing things in the company.

As can be seen from the assertion stated above, if things are not done properly, then the whole setup can be counterproductive hence the need for experience personals to be in charge. This conforms with our literature which noted that for six sigma to be successfully implemented organizations essentially require competent and trained manpower for conceiving and running six sigma projects.

Extensive training for some of the selected competent people in the organization is necessary to produce any noteworthy Six Sigma results. This view is further upheld by Cyger (2015) who argued that “one cannot expect to significantly reduce costs and increase sales using Six Sigma without investing in training, organizational infrastructure and culture evolution”. Since technical expertise is crucial to the successful implementation of Lean Six sigma, high level training for personals that will be involved in the project becomes inevitable.

➤ **Lack of Qualified Personals**

This point is connected to the one raised above. Since it is the duty of the trainers to introduce and follow up the Lean Six program on employees, it becomes imperative for those handling the training to know and understand what they want to achieve. As Participant 4 pointed out,

You know this methodology a lot, people know about Lean Six Sigma. And they very accommodating, even when you're working with a team, and with people outside your team when you want to get an information, they're happy to help because they know you're helping them too. I think this concept has been in pharmaceutical industry for long, and people understand, you know, that good changes are coming so they are willing to help you. As long as you talk, you don't take them away from their daily task, too much. So, it comes back to the point, you need to have a team, a designated team to do this implementation. (Participant 4, 2019)

Essentially, the findings of this research revealed that the major reason why the implementation of Lean Six Sigma fails is due to professional trainers.

➤ **Management Apathy**

Critical to the success of Lean Six Sigma is management commitment to it. The findings of the study revealed that for lean to succeed, the top management must show sufficient interest in its implementation. Lean Six Sigma as noted by Raghunath and Jayathirtha (2013) is seen as just a passing management fad by some organizations. However, innovative leadership is required by organizations at all levels for growth and development.

Participant 3 notes that a decision has to be made from above. We need to take this Lean Sigma project. Similarly, participant 1 notes that both managers and other people like associates are very important in implementing the Lean Six Sigma, like everybody has to be involved. This implies that when the top management is not committed to Lean Six Sigma, the program will fail. As one participant rightly noted, if your management aren't involved, actively participating, it will fail, it will fail every single time (Participant 4, 2019). To this end, the argument here is that, when the company has a culture of not paying adequate attention to both internal and external customer needs, then Lean Six Sigma implementation is likely to fail.

➤ **Complex Bureaucracy**

The study found out that the bottle neck found in most company's acted as a barrier to Lean Six Sigma implementation. The chain of command found in some company's slow down the implementation process. The time to achieve certain targets is unnecessarily extended due to complex bureaucracy. The stress of passing through so many processes in order to get a simple task done can sometimes be frustrating to the employees and this may discourage them from embracing the Lean Six Sigma, viewing it as an attempt to increase their work. Participant 3 notes that when this is the case, what people do is that "they go away so they don't get this process". Following from the above, complex bureaucracy has been identified as a barrier.

➤ **Resistance to Change**

Resistance to change was identified as one of the greatest barriers to Lean Six Sigma by respondents. It was discovered that most employees and management failed in the implementation of Lean Six Sigma because they were too committed to the old ways of doing things and were unwilling to change. All five (5) respondents acknowledged to this. Participant 4 noted that "It's absolutely the attitude and the willingness to change" that is the most important thing.

The application of Lean Six Sigma comes with a lot of change. Where employees feel that the changes applied will take away or increase their work load due to lack of or poor orientation, there is all likelihood that the program will be resisted. Respondents have noticed that when this happens, then the tendency of the program failing is high. It is in line with this that resistance to change has been identified as a barrier to the application of Lean Six Sigma.

Qianmei (2008) agrees with this argument where he starts by stating that change is always faced by resistance. Most of the resistance and problem is found to be originating from the leaders and major stakeholders. Similarly, Nathan (2019) in his work Five Obstacles to Implementing Lean in Small Business identified "underestimating employee attitudes/resistance to change" as one of five major obstacles to implement lean within small businesses

In the same vein, Participant 3 notes that this concept has been in the pharmaceutical industry for long, and people understand it, that good changes are coming so they are willing to help you. "As long as you talk, you don't take them away from their daily task,

too much. So it comes back to the point, you need to have a team, a designated team to do this implementation”. Participant 4 agrees with this line of thought as he notes that he makes everybody in the organization understand or try to make them understand the changes are to make their jobs easier, to get better results, and not to get more work out of the market.

Thus, Grover et al (2010) argued the lack of a clear strategic framework to be the cause of resistance to change from both the management and the staff members (Grover et al 2010). To this end, Kandlossui advises that it is imperative for formal communications to be well recognized by the institute officially. Information and instructions should be passed either from up downwards or down upwards along the channels of formal communication (Kandlossui, 2010)

4.3.2 Facilitators

Facilitators refer to the factors that aid the smooth application of the Lean Six Sigma program in the pharmaceutical companies. Four of these were identified: application of multiple tools, team work, and management commitment to Lean Six Sigma and adaptability to change.

➤ Application of Multiple Tools

It was discovered that the application of multiple tools aid in the implementation of the Lean Six Sigma as against the use of one tool. This was as a result of an overall improved performance recorded with the use of multiple tools. The application of multiple tools ensures that every aspect of the lean program is covered. Also, the quick result noticed in the shortest period encourages both employees and top management to follow through. To this end, the application of multiple tools was identified as a facilitator. On the down side of this however is that the application of multiple tools cost a lot of finance in terms of training and may discourage users. But where finance is readily available, multiple tools are facilitators. This was revealed by a participant who noted that

There's a lot of training available for all the different tools of Six Sigma.

So we've got both internal training within the plant where we are use to training tools such as 5S or Kaizen, things like that. But then we also have

external training available, where you can obtain the different belts, you know, your yellow belt, your green belt, your black belt...for example, my own team has used to improve performance

Mallick, Ahmad and Bisht (2012: 13) in their study of the Barriers and Enablers in Implementation of Lean Six Sigma in Indian Manufacturing Industries highlighted the application of less tools as a barrier. This view might have been influenced by the fact that most of the tools were specially designed to improve specific areas

While this gives the impression that the combination of multiple tools gives faster result, it also points to the fact that more and more people will have to be trained on how to make use of those tools which could translate to huge financial burden for small business in the pharmaceutical industry. This argument gives credence to our earlier claim that lack of finance remains a major barrier to the successful implementation of the Lean Six Sigma. While the cost does not necessarily stem from the tools themselves, the problem arises at the level of training employees on how to use them. This is in lieu of the fact that one major barrier that have been pointed out by previous works is the issue of poor understanding of the six sigma which has led to poor execution.

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➤ **Team Work**

As oppose to individualism, team work is a great facilitator of the Lean program. It was found out from the responses that for Lean Six Sigma to work, everybody must be involved in the process. All five (5) of our respondents acknowledged to this. This position has also been confirmed to be the case by other studies. It is not just an employee's thing or top management thing, but everybody's thing.

Participant 1 notes that both managers and other people like associates are very important in implementing the Lean Six Sigma, like everybody has to be involved. In the same vein, Participant 2 expressed the same view to back up the claim when he asserted that "It's all levels, and it's like from our associates, which would be our technicians or our operators who work on the process right the way up to senior managers. And so everybody is involved in our, I suppose our improvement programs." This is the general sentiment cut across all five (5) of our respondents.

➤ **Management commitment to Lean Six Sigma**

It was discovered that one of the major reasons why the Lean Six Sigma program fail is because most management are skeptical of the program due to lack of knowledge about it or as a result of other programs already in place. This point is tied to the one above because even when management believe in the program, its application cannot be left solely for the employees. Top management must dedicate time and resources for it to succeed. To this end, the commitment to the Lean Six Sigma program by management has been identified as a facilitator of the program.

➤ **Adaptability to change**

This is the direct opposite of resistance to change. Comparing data from this study with that of other studies revealed that when employees and top management are willing to change Lean Six Sigma tends to be a success than when they are resistant to change. This shows that adaptability to change is a facilitator of the successful implementation of the Lean Six Sigma program. This view is supported by the response of all our respondents who acknowledged to this. Take for example Participant 1 who noted that “no matter how if the customer or if the management wants something to happen, if the associates or if other people that are not managers don't want to do it, it's not going to happen. This view was also shared by Participant 4 who argued that the success of the Lean program “would be based on the individual, so their attitudes and aptitudes towards change. So they have to be willing to change. And they have to be able to influence and make the changes required”

The results are summarised in Table 3 below

Barriers	Facilitators
Lack of finance	Application of multiple tools
Trainings	Team work
Lack of qualified Persons	Management commitment to Lean Six Sigma
Management Apathy	Adaptability to change
Complex bureaucracy	
Resistance to change	

Table 3 Result summary

CHAPTER FIVE

5. CONCLUSION AND RECOMMENDATION

5.1 IMPLICATION OF FINDINGS FOR THE RESEARCH QUESTION

The results from the analysis significantly addressed the study's research questions and helped to achieve its goals, which were to: establish how LSS was implemented in pharmaceutical companies in Ireland, identify the factors that aided its implementation and the challenges encountered in the implementation of LSS in Irish Pharmaceutical companies. To this end, the implications of findings for the research question are that:

- The major factors that acted as barriers to the implementation of LSS in Irish pharmaceutical companies were identified. They included: lack of finance to train the required personals to handle the program which led to a shortage of qualified

manpower. Similarly, complex bureaucracy that unnecessarily multiplies the steps taken for a simple task to be done discouraged employees on accepting LSS thereby affecting its successful implementation. Finally, management apathy to LSS was also identified as barrier to the implementation of LSS in Irish Pharmaceutical companies. The findings of this study are similar to the research conducted by Eirin et al. (2016); Raghunath and Jayathirtha (2013) who listed the following barriers of Lean implementation and Six Sigma irrespectively as; Lack of knowledge about tools, Lack of finance, poor training, lack of management commitment

- As regards the factors that aided the implementation of LSS: adaptability to change, team work, the use of multiple tools and management commitment to LSS were identified as the most important.

5.2 CONTRIBUTIONS AND LIMITATIONS OF THE RESEARCH

This study was structured to provide insight into the facilitators and barriers that Pharmaceutical companies based in Ireland encountered while implementing LSS. To this end, the specific objective of the study was to identify the constraints, failures, promoters and success factors associated with LSS implementation in Irish pharmaceutical companies. Following from the above, the study made the following contributions:

5.2.1 Contributions to Knowledge

- While the literatures on the barrier and facilitators of Lean manufacturing and Six Sigma are rich, there is however none to the best of my knowledge that have looked at the barriers and facilitators of Lean and Six Sigma combined in pharmaceutical companies in Ireland. This research is thus, first of its kind.
- Secondly, the discovery of the use of multiple tools as a facilitator of LSS is first of its kind and a major contribution of this study to knowledge.

5.2.2 Limitations of the Study

- The first limitation of the study was in sourcing for the research data. Getting respondents for interview was very difficult due to their tight schedule and low

response rate. Consequently, only five (5) participants were used for the study. While this does not invalidate the findings of this work in any way as data saturation was reached, it however limits the generalization of the findings significantly.

- Secondly, the study was limited in scope as it only covered the implementation of LSS in pharmaceutical companies in Ireland.

Strengths: The limited scope of the research helped the study to be more focused rather than vague. Thus, an in-depth study was carried out on the phenomena under investigation and data saturation was reached after first 4 interviews. Also, the interview method utilized ensured that the author had a first-hand information from respondents.

5.3 RECOMMENDATIONS FOR PRACTICE

The application of LSS has been noted to improve efficiency and eliminate waste in companies. While this is the general sentiments shared by the literatures (Raghunath and Jayathirtha 2013; Abdullah and Patrick, 2016), its application has proven to be problematic due to a lack of understanding of what LSS really represent (Abdullah, and Patrick, 2016). To this end, the following recommendations for practice are made from the research findings:

- In order to enjoy the benefits of LSS, pharmaceutical companies are encouraged to invest a lot in training. Even though the project might prove capital intensive at the beginning, studies have revealed that it is financially rewarding at the long run.
- The results of this study revealed that money alone doesn't result in LSS. Thus, in addition to investing in training, the top management are also advised to be involved and committed to LSS to experience faster result.
- Finally, this research discovered that complex bureaucracy acted as a barrier to the successful implementation of LSS. To this end, companies are advised to shorten the steps to overcome bureaucratic hurdles such as the time it takes for a task to be completed to the shortest possible time to get the best out of LSS.

5.4 RECOMMENDATIONS FOR FUTURE RESEARCH

The set aims and objectives of this study were to establish how LSS was implemented in pharmaceutical companies in Ireland while also identifying the factors that aided its implementation and the challenges encountered in the implementation of LSS in Irish Pharmaceutical companies. While recognizing the limitations of the study, it is my utmost believes that the aims and objectives of the study were largely achieved. However, the scope of the study which greatly limited the applicability of this research endeavour has been identified as an area future studies should look into. Following from this, the following recommendations are made for future studies:

- That the scope of future studies should be expanded to cover other industries. Also, should compare the success rate of LSS across states and industries to see if there are factors in certain industries that affects its implementation.
- Due to our inability to get more respondents for the study, there were interesting areas such as the areas explore by Cyger, (2019) on his work on Six Sigma Costs and Savings and the impact of external and internal training on the implementation of LSS that we missed out on. Thus, future studies are advised to look into this area.

5.5 FINAL CONCLUSION AND REFLECTIONS

Following from the analysis of our data and the findings of this study, the study concludes that the major barrier to the successful implementation of LSS in pharmaceutical companies in Ireland is a lack of understanding as to what LSS really is due to poor training. Also, the lack of qualified personals owing to the unavailability of the needed resources to sponsor for the required training is also a challenge to the implementation of LSS. This knowledge gap makes employees and management to resist the program not really knowing its benefits. To this end, the research concludes that adaptability to change, team work, the use of multiple tools and management commitment to LSS was crucial to its implementation.

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APPENDICES

APPENDIX A

Barriers and Facilitators to Lean Six Sigma Implementation in Irish Pharmaceutical Companies.

Research questions

1. Please describe your role in your organisation?
 - How long have you worked there?
 - What department do you work in?
 - Do you manage staff?
2. How is Lean Six Sigma Implemented throughout the Organization you work in?
 - What LSS tools are used i.e. 5S system, Kaizen, Value Stream Mapping
3. Who in your organization plays a role in Lean Six Sigma implementation?
 - Managers
 - Associates/operators (the staff that work on the production line)
4. Has LSS impacted your company's business performance?
 - Has waste been eliminated, and money saved through the implemented of LSS?
 - Has LSS improved customer satisfaction?
 - Has LSS impacted the overall quality of the products your company produces?
5. What factors have facilitated the implementation of LSS in your company?
 - Company culture
 - Top management

- Buy in from staff

6. Has your company experienced challenges when implementing Lean Six Sigma?

- Hard to implement LSS and adhere to regulatory policies
- cost of implementing LSS
- Lack of input from staff?

APPENDIX B

Barriers and Facilitators to Lean Six Sigma Implementation in Irish Pharmaceutical Companies

Dear Sir/Madam,

My name is Racheal, I am a student in the MSc in International Pharmaceutical Business Management in Griffith College Cork. Under the supervision of Dr Caroline Hurley, I am conducting a research study to investigate the barriers and facilitators of Lean Six Sigma implemented in pharmaceutical industries in Ireland.

I wish to invite you to participate in the study which involves **one 20 minute** face to face or telephone interview. The aim of the interview is to get your experience of implementing Lean Six Sigma in the pharmaceutical industry, and to get the barriers and facilitators of Lean Six Sigma implemented in your company.

Any information collected during the course of the interview will be maintained on a confidential basis, your name will not be disclosed, nor will details of your answers.

If you are willing to participate, kindly suggest a date and time for the interview, between the 10th of July to 10th of August.

If you have any questions, please do not hesitate to contact me on 0833338560.

Thank you for your attention.

Kind regards,

Racheal Ojuederie Eseoghene.

APPENDIX C

TITLE OF DISSERTATION

Barriers and Facilitators to Lean Six Sigma Implementation in Irish Pharmaceutical Companies

- I..... voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves asking of several questions to assist in the research.
- I understand that I will not benefit directly from participating in this research.
- I agree to my interview being audio-recorded.
- I understand that all information I provide for this study will be treated confidentially.
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I understand that disguised extracts from my interview may be quoted in the dissertation write up and presentation.

- I understand that if I inform the researcher that myself or someone else is at risk of harm they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.
- I understand that signed consent forms and original audio recordings will be retained in the possession of school authorities and student's possession, and can only be accessed by student and school authority until the exam board confirms the results of student's dissertation
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for two years from the date of the exam board.
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information. Names, degrees, affiliations and contact details of researchers (and academic supervisors when relevant).

Signature of research participant

Signature of participant

Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

Signature of researcher

Date

APPENDIX D

Barriers and Facilitators to Lean Six Sigma Implementation in Irish Pharmaceutical Companies

Interviewer: Student

Interviewee: Bio of participants are seen in chapter 4.1.1 data

Interview Setting:

Participant 1- Interview Conducted at 9:04pm on the 12th of July 2019 via telephone call

Participant 2- Interview conducted at 9:21pm on the 14th of July 2019 via telephone call

Participant 3- Interview conducted at 3:30pm on the 19th of July 2019 via telephone call

Participant 4- Interview conducted at 10:15am on the 29th of July 2019 in an office setting

Participant 5- Interview conducted at 4:30pm on the 10th of August in an office setting.

Total File Duration: 1hr 54 minutes.

Audio

Transcribed: August 3rd, 2019

[01:17]

Interviewer: Can you please introduce yourself, your role in your organisation like how long have you worked there? What department do you work in? Do you manage staff?

Interviewee 1: So, I am a material engineer in the materials and surface technology department. And I am in the 3d printing team. So, I'm working on launching some invalidating some 3d printed product. And I've been working in this company for about nine months at the moment.

Interviewee 2: And so, my role in the organization is I'm the operations director, and also, I have responsibility for the leadership of biological manufacturing activities. So, in my role I have responsibility for and the manufacturer of the commercial portfolio of biologics products, and also the clinical portfolio of biologics product. Both clinically and commercial. I have six direct reports and I have about 190 indirect reports.

Interviewee 3: So, I'm working for Eli Lilly, Kinsale at the moment. I am working as C and Q engineer. Okay. So, conditioning and qualification engineer is my role. So, I have been working for this role since March this year. So, it's relatively new to me. But I have been working for small molecules, and the biopharmaceutical industry for last 10 years. More than half of my work has been heavily involved in project management. So currently I'm managing projects, it's more or less engineering projects. So that's a big change for me. My previous roles, more focused in processing, production and manufacturing, that aspect of the pharmaceutical industry and this is the engineering side.

I am not a people manager at the moment. But I'm managing projects. So I am working with people. So basically, I do scheduling, but I don't deal with people management side, if you don't get me is only for the project, and the people within my projects. So they would have their own line manager. So I only deal with them from projects point of view

Interviewee 4: So my role at the moment is Lean Six Sigma site lead, with Vivasure Medical. I've been there 11 months at this stage. Recently, I was asked to take on more responsibility. So I'm actually managing the supply chain as well at the moment. And I have two people reporting to me.

Interviewee 5: I, I'm actually known as production line technician, and whatever production is going on in the company we try to take care of doing this task in the production sequence and style and how to implement some of the directives given by the managers

[2:10]

Interviewer: How is Lean Six Sigma Implemented in your Organization, what are the tools that are used for example, 5S system, Kaizen, Value Stream Mapping

Interviewee 1: so in our organization, there's a lot of training available for all the different tools of six sigma. So we've got both internal training within the plant where we use to training tools such as 5S or Kaizen, things like that. But then we also have external training available, where you can obtain the different belts, you know, your yellow belt, your green belt, your black belt, where the official authorities were to train our own staff, the staff is interested, interested in doing different tools that I'm aware of that, for example, my own team has used to improve performance would be things such as 5S, they've got Kaizen, we've got FMEA process, 5 Whys, things like error proofing or you know, pokes-yoke, things like that.

Interviewer: Who organizes the training?

Interviewee 1: It is organized by our own organization. I suppose, we have a Lean Six Sigma team and the team would organize the different training for you've got your 5S team that is, for example, is just looking at using the 5S tool of Lean Six Sigma and the team themselves would then train a person from each area because obviously you can't have one team going all over the building, you will have one person from each area. And if there's a new person, a convener or a person needs, the core 5S team will come and train the person in implementing and using the two.

Interviewer: So this training is like every staff that comes in an existing staff?

Interviewee 1: So you would, if you are interested, you can be part of the 5S team so that would be more of a hands on training where you actually go into the 5S, but we also do have read and understand training for you, where you get trained online, on how to use the tools. You would read or have different kind of quizzes and questions on the different tools that would help you to use them.

Interviewee 2: So, I suppose we have implemented all of the tools or most of the tools anyway, in all of our standard business processes. And so we have implemented this, we have implemented Kaizen, we have implemented root cause problem solving. And, and, and what we call root cause analysis, which is RCA. And we have also deployed VSM, which is value stream mapping. And we also have used time in motion studies. So, I would say, you know, the majority of the Lean Six Sigma tools are actually used within the organization.

Interviewee 3: The number of tools we use are the most common ones I suppose. I suppose the ones I have been dealing a lot with is Pfizer. And then of course, Kaizen as well. The thing is lean manufacturing and Six Sigma are two different concepts, two different methodology. So, we call them Lean Six Sigma, because they are used together a lot of times. So, for Lean Six Sigma and for Lean manufacturing, I suppose is to mainly look at the process itself. There is a number of tools you can use in Lean manufacturing, like Pfizer and Kaizen. And then I suppose they are kind of more informal tools we use, but the even the methodology itself is pretty powerful right and folly manufacturing. I suppose in last two decades, if you really want to see how the Lean Six Sigma evolved in pharmaceutical industry, it has been developed enormously in last two decades. So, the major areas I have seeing for like the most of you know, because they are our engineering from manufacturing era right. So, so, without a doubt, so, manufacturing production and processing are the main area and they are always a key areas for the industry to develop and manage and Lean process. I also see a warehouse and the laboratory in all the supplies as Kaizen towards us in, in this era, engineering is pretty much everywhere, like the name is right , and Kaizen and Pfizer like warehouse lab, housing safety, even office, everywhere really. It's an improvement tool and basically for more efficiency.

Interviewer: what of Six Sigma to like maybe voice of customer matrix?

Interviewee 3: If you get into the pros, I will talk about both has a lot because it is a processing tool for processing it has the different steps involved, then you can eliminate your non value added activities, right? You have to have a group of activities for this to

work so if you see a Lean project as a whole site let's say Eli Lilly, and consultants. So they do work on that kind of massive projects, from maybe health and safety perspective. But most commonly we take on much smaller projects. So we only usually deal with individual process. Take I just gave an easy example. So if you're probably familiar with the lab project, right. So if a lab technician, wants to source an instrument for the lab, this instrument chromatography, it's so important for the lab, I want to buy Neil HPLC machine, right? Basic, okay. So, what does he or she need to do that?. I can give example before Lean, right and after Lean. So say before Lean, the lab technician is actually real life example I used to work with. So say before Lean process, the lab technician has to set up a meeting with his or her manager first to state the requirement of this instrument. We do need this instrument for reason, ABCDE, right?. So the manager then goes away and fill out a form right? For the senior senior management, approval, right. So they need go level above, right. And then the lab technician or a lab manager ask for a price quote from the instrument vendor. So then they will have the price let's say 50 K, right? For this piece of instrument, then they will submit another form, right with the price quotation and the lab request requirements justification say Oh, how much is the instrument going to cost? why we need these instruments basically to finance department for pre approval. Once it's pre approved by finance, another form is sent to the senior management to sign right, and then sent back to the finance office. That's for proper approval, the final approval. Once it is approved then the purchase order is generated by the finance department then the lab technician or the lab manager can pass this purchase order to the vendor, and then the order is placed. And then we all waiting for delivery. I suppose there's probably other things going on but that's probably seven, or eight or nine steps. Ordering a piece of instruments. So what people do is, they go away so they don't get this process. We asked ourselves which steps we don't have to go because it's time consuming and it's back and forth and many forms you have to fill out. So usually in the project itself, we look at them, we look at step with cut out all those ones we don't need. We don't need to go to so after that. So we did basically really simplified the process. So I would like to talk about instruments less than 250 K, right? So anything above that is probably more and you probably need more people to sign it, because it involves more people is big capital thing, right? So if it's less than 250 K, so

once the lab technician wants to buy this piece of instruments, technician will ask price quotation from the instruments vendor. Right? Because you don't go to your manager, you don't go to the finance, you don't deal with anybody else. So you get a price quote. So then the lab technician was submit of form, with the price code, and the justification to finance departments. And in the same form, you have the senior management sign included. So both finance and senior management, need to approve in one form and once it's been approved, happy house. Usually the senior management signs off and finance. The finance generates a purchase order. So the purchase order would come back sometimes to the lab technician, but a lot of times the finance just pays the purchase order and then it didn't have to come back to the technician. The order now is placed. So it's much shorter. We are all kinds of you know, comfortable with whatever we have been doing, nice you sit down and break them into different steps. And just cut out

Interviewee 4: What I'm working on is quite unique at the moment in that has been about a year and a half ago, clinical approach to developing products. In the last year and a half, it has been on commercial process, and selling the product in the European market. And we're also looking to get FDA approved, and sell product in the FDA and Asia. So at the moment, it wouldn't be very mature at all in terms of any lean tools, or indeed Six Sigma tools. So there are a number of tools being used not overtly, kind of by default. So we have a 5S system, although it's not really managed our structures, we just have workplace organization. So the engineers have set up the lines, and they're kept to the standard stage. Okay, and we will use the structure of problem solving. So again, it wouldn't be in an overt manner or standard format. But we have a number of engineers that would, find the problem, interlude actions, develop the root cause or lack I think. So we use the 5 Whys, and the fishbowl diagram. And one of my roles at the moment is to develop structures in project management office, to help us select what are the most partners projects for the business, to match them up with available resources and to develop the project management structure to ensure that those projects are successful and run on time. So you'd be looking at your project charters, cost benefit analysis, work breakdown structure, project review process, your four panels,

stakeholder management. So just to summarize, there's a lot of tools being used, but not over here. Maybe not organized or standardized.

Interviewee 5: Alright, it's not just one tool we tend to combine a lot of tools together we use a lot of tools in my company, like we use the 5s and the Value Stream Mapping and the Project Chatter, the Ridge Cost Analysis, we also use the Poke Yoke as a tool. Alright notable I would like to talk about just one of the tools the 5s alright! Because it's very easy to explain and it's simply: Search, Sot, Shine, Standardize and Sustain where you have, So basically the use of the 5s is such to eliminate waste and make sure everything is working and concurrently and smoothly whereby we eh put things in order and there's no ambiguity, there's no confusion where we're doing our work.

[3:20]

Interviewer: Who in your organisation plays a role in Lean Six Sigma implementation? Is it more of the Managers or it's done by everybody, like a collective work?

Interviewee 1: So, I think both managers and I suppose and other people like associates are very important in implementing the Lean Six Sigma, like everybody has to be involved, it's part of the culture here. So everybody's effort is required for the performance improvement. So you have things like you have finance teams that are usually made up of both managers and associates, who would monitor different areas. Ideas would usually come from those who are working on the process constantly, which would be associate but then these ideas can be driven by people who have more time to drive these and have more visibility, like managers for the improvements to be implemented.

Interviewee 2: It's all levels, and it's like from our associates, which would be our technicians or our operators who work on the process right the way up to senior managers. And so everybody is involved in our, I suppose our improvement programs.

Interviewee 3: So usually, right, the most common setting is we have a project team, right? There is Lean project team. Take the previous lab thing, for example. In that team, you have pulled the team lead, who has to be green belt. And then it's green belt above. So there's project and there's project lead, sponsor you use your best belt, project manager who is kind of helping the team lead, guiding the team lead to the project and then you have stakeholders who benefit from the project and then you'll have team members.

So usually you have functions like, say, take the previous one, for example, you'll get a lab technician, right? He or she will be the lead cuz that's probably, you know, make sense, because she's involved quite a bit in the process, right? You could have the finance person as a team members. You can also have the lab managers, team members as well. Right? And then the senior management can be whoever oversees their project, and who benefits from this project can be the stakeholder. So you do have a team. It's not like managers, operators, that section, that kind of structure isn't common for Lean projects, because we do need people from different it's more cross functional project tonight. So usually I have been working on projects involved in eight or nine different functions, so can be a procurement, regulatory, quality is a need. And our vendors, and then our different labs, you know, research labs, is just enormous, like it's different people need to be involved in this process.

Interviewer: So when getting people involved, are there specific qualifications you look out for, like Green Belt?

Interviewee 3: Good question. So the lead has to be green belt or above. Usually, the sponsor is the black belt. The team members, you don't have any questions at all. And you need to know their own area. So we don't usually need any qualification from them.

Interviewee 4: Yeah, that role would fall to me, the way I would do is, is, I would target the change agents within the organization. And in my experience, it's not always a particular role. What I would do is I would know, the changes within the organization, and I would target them specifically to proliferate the Lean. So it would be based on the individual, so their attitudes and aptitudes towards change. So they have to be willing to change. And they have to be able to influence and make the changes required. So

throughout my experience, I find that if the individual doesn't want to change, you can't really force it upon them. So what I do then is I have enough people within the organization making the change, so that they have to come along with you, they have to change their attitude has to change towards. I make people understand why they need to change, changes for the better, you know, to try and affect the culture. So I make them understand or try to make them understand the changes are to make their jobs easier, to get better results, it's not to get more work out of the market, push them harder, or to make them go faster, but to make their jobs more easier to perform. So at the end of the day, they're not as fatigue, they're not as stressed, there's not a requirement for overtime, it's just to give them the tools, they need to do their job well without any problem. So that's the way I command change, you know, it's not to get five extra units out to them at the end of the day, and then ask for another five. It's, what can we do to make this job easier than if the job is easier? Of course, you can make five more, it's easy to do that. So the change is a positive thing.

Interviewee 5 : Lean Six Sigma implementation is normally a top to down approach, everyone is involved in the implementation all employees are using all the tools together eh the manager sends in sort of an instruction on how it is going to be used and everything is being implemented so it's eh up to down approach so implementation is done by managers and operators.

[4:30]

Interviewer: From your own perspective, would you say Lean Six Sigma has improved your company's business performance like in terms of customer satisfaction and product quality. Applying this tool has it caused an upliftment and improvement in the business performance?

Interviewee 1: So I definitely think it has some my own opinion. For example, I'm working on a project where we're launching a new product and we use different Lean Six Sigma tools, such as, you know, Pareto charts and things like that, to reduce crafting and to allow a better process. So sometimes we review value stream mapping, to allow for a faster a better process flow, meaning there's no resources wasted. So I think it's definitely improved the business performance of our company.

Interviewee 2: Rachel, it's slightly difficult to answer this question, because we have a system, which is specific to Johnson and Johnson, and overlapped significantly with Lean Six Sigma. And it's basically called the Johnson and Johnson production system, in short JJPS. This system has a lot of the elements of a Lean Six Sigma framework. And, however, that's the system that we use to deliver our business standards. And I suppose that that framework of the Johnson and Johnson production system has 10 business standards. And that's really what we have here used to drive and our cost improvement programs within the business, to drive our safety programs within the business to drive standardization and all of our processes, you know, right down to managing our price performance, and managing our standard work. It's all done through the Johnson and Johnson production system. So it's not specifically aligned to Lean Six Sigma but there are a lot of the tools that Lean Six Sigma would have provided we would use as part of the Johnson and Johnson production system. Okay, yeah, yeah, cuz I remember my school, we had an excursion to Johnson and Johnson last year. Yeah, we met Amy White. I think that's her name. And I think she said something about this. I just remembered. Amy White is this. Yes, yes. I told Yeah. Yeah, sure. Yeah. Amy works in my team.

Interviewee 3: The ultimate goal of manufacturing cost saving and increase efficiency at the same time. And then sometimes you include the safety as well, you know, it's more like if you do 5S, if you do Kaizen you can increase safety. This can have other benefits as well. I suppose that that's the goal. So of course, yes. So to answer your question, waste has always been eliminated and this is cost saving for sure. So I suppose how much? that's more like project management Lean six sigma. So with every project,

and you estimate how much cost saving, say 40%, or 20%, or 5%. To me that's right in front before you even start you need to have all this information ready to go. So you talked about customer satisfaction? That's more about our product quality. Our customer service is not monetizable for pharmaceutical industry. So six sigma is a quality tool, basically, it doesn't make sure we have very little default. So that's the ultimate goal of six sigma. To answer your question, yes. So that's a quality thing.

Interviewee 4: At the moment, it would be hard to say because my role will be to develop those with the commercial team, in my previous history of holding similar roles in other organizations, I would say it absolutely has an impact on business performance and customer satisfaction. So in particular, 5S systems, project management, and awareness of the seven ways of lean and daily Kaizen as well and structured project management.

Interviewee 5: I suppose it has because it is a proven strategy alright because apparently we have eliminated waste, we have spent less time working on the line and there's efficiency in the product and our customers are satisfied it's all proven so I will say ye

[5:16]

Interviewer: What are the major factors that have facilitated the implementation of LSS? Is it more of the company's culture, top management or buying from staff?

Interviewee 1: So what I think is, it's the company culture, I think, no matter how if the customer or if the management wants something to happen, if the associates if other people that are not managers don't want to do it, it's not going to happen. So it's the company culture. And I believe the culture here in my own organization, is that is very, very focused on the six sigma and everybody's happy to work together to improve

different processes using the tools of Lean Six Sigma so I think it's the company's culture in my opinion.

Interviewee 2: I suppose, it's the culture within the organization. So it's a culture with a mindset for continuous improvement. So it is absolutely really doors, and facilitate any of the adult be the methods or any of the systems that are focusing on improving your your process, improving your systems, improving your environment. So I think it's the culture that we have within our organization. I suppose the second thing is getting everybody involved, Rachel, it's not a being driven from management down to the staff, it's actually both, and I suppose the full spectrum of your, of your talent pool or your employee pool he who is actually working on this together, and as you know, so it is, top down, bottom up, which whatever you want to look at it, but it's really, essentially, everybody being impacted. And I suppose the other piece is that the responsibility is across everybody in the organization, it's not just the responsibility of your technicians, or the responsibility to your senior management. And, and I suppose, what we have seen is where individuals take responsibility for deployment of a JDPS standard, or the use of Lean Six Sigma tool like, the implementation of our Kaizen and Denver works. And, you know, and using our root cause, problem, and analysis, and to investigate issues and problems. And I suppose, when actually people take responsibility, and to work and to deliver a particular element, and then you get the volume, as opposed to somebody directing you to users. And if people can see the benefits from from the tools they're using, and then, you know, you get greater volume. So I would say that, you know, they're full of the factors that I would think, and it'll have made the implementation of, you know, the deployment of the tools easier.

Interviewee 3: I suppose top management. So a decision has to be made from above. We need to take this Lean Sigma project. And company culture? Yes. I suppose people benefit, they have benefited from this process a lot. You know, this methodology a lot, people know about lean six sigma. And they very accommodating, even when you're working with a team, and with people outside your team when you want to get an information they're happy to help because they know you're helping them too. I think

this concept has been in pharmaceutical industry for long, and people understand, you know, that good changes are coming so they are willing to help you. As long as you talk, you don't take them away from their daily task, too much. So it comes back to the point, you need to have a team, a designated team to do this implementation. You cannot give this as people's extra work because people have daily jobs to do. And then once you do a project, you expect to complete the project at a certain time, you probably have like, one lab technician work four hours a day out of eight, as your team member needs to that. So that person didn't have to do full time, right? She need to do Lean Six Sigma project. Time had to be given to that person, right. So he can he or she can only do four hours of daily work.

Interviewer: What are the challenges? You think companies experience when implementing Lean?

Interviewee 3: So a decision has to be made from above. We need to take this Lean Sigma project. And company culture? Yes. I suppose people benefit; they have benefited from this process a lot. You know, this methodology a lot, people know about lean six sigma. And they very accommodating, even when you're working with a team, and with people outside your team when you want to get an information, they're happy to help because they know you're helping them too. I think this concept has been in pharmaceutical industry for long, and people understand, you know, that good changes are coming so they are willing to help you. As long as you talk, you don't take them away from their daily task, too much. So it comes back to the point, you need to have a team, a designated team to do this implementation. You cannot give this as people's extra work because people have daily jobs to do. And then once you do a project, you expect to complete the project at a certain time, you probably have like, one lab technician work four hours a day out of eight, as your team member needs to that. So that person didn't have to do full time, right? She need to do Lean Six Sigma project.

Time had to be given to that person, right. So he can he or she can only do four hours of daily work.

Interviewee 4: Well, it is the awareness from top management of the value of having a change agent in there. And also empowering the change agents to make that change. So if your management aren't involved, actively participating, it will fail, it will fail every single time. So part of the challenge, I have noticed in a role like mine is every single member of the management team, I've been in fantastic places where one or two of the managers wouldn't necessarily be bought into us. And the biggest challenge of the implementation is to get the culture sets with those few managers who don't want to change. So that's where I spend a lot of my focuses with the management team, to teach the tools and to select the change agents and development. That's the easy part. It's absolutely the attitude and the willingness to change from the top management. If you have that, you will be successful.

Interviewee 5: hmmm, okay how do I go about that! I would say more of the company culture alright, proper coaching and teaching by more experience personal and management all these together has led to eh a successful implementation of Lean Six Sigma.

[6:10]

Interviewer: Have you experienced any challenge when implementing Lean Six Sigma? You know sometimes implementing Lean Six Sigma and adhering to the GNP and regulatory policies can be tasking from what I read online.

Interviewee 1: So myself, I haven't seen it being heard, because I mean, I came here nine months ago, and in my own team, Lean Six Sigma is used pretty much every day different tools of Lean Six Sigma is used all the time. So I see I feel like my own organization is very good at implementing it or I suppose it has already been implemented in the culture of this company. So I just believe it has not impacted my

organization but I think there are always challenges and probably when it was first introduced initially into the company, it must have been not as easy. But our staff is very good at following the different tools so I have not seen the challenges.

Interviewee 2: And, not really, in terms of implementing, in some instances, we have found it hard to sustain us? Because, you know, I suppose, probably, like every organization Racheal to be honest with you, you know, we're all the time and looking to improve, you know, how we do our business. And so we move from, you know, one program to another very quickly, and sometimes we don't actually let a system or a process bed in and look at, you know, what we should do? We just move on to something else. And so, actually, I suppose, you know, implementing is never a problem. It's more about sustaining peace.

Interviewee 3: Lean projects are not different from other projects, right. It's all three most important factors, time, cost, and quality. The most important factors for implementation, and as you know, like quality of product cannot be compromised in this industry. This is the base for all process so we don't sacrifice any quality. What we can pay is time and cost. Once we have our milestone set, we have our time set, we have cost savings in our head. And we know how much we're going to save, we predict that we estimate that. And I suppose the most important thing is to get your team members who are capable, you know, I suppose they are right members, they know their own areas so we can map the process, you know, so once the process is mapped, it's quite the structured thing It's quite systematic, you take that step by step. And I think the reason we need people is we want to map the process, total mapping, w don't want to miss any step and we don't want to get the wrong timeline for each step so that's quite important. And the cost wise, I suppose is another really important thing , you know, there's a lot involved when you work with finance.

Interviewee 4: wouldn't say cost because a lot of the tools are free. To take the time, the only cost is the cost to get people together, you know, away from their day to day jobs, to make the time to make the improvements. That to me, the number one thing is the

willingness to change, right, that's the biggest factor that will hold up things. And the second thing then is actually get the resources freed up to do the exercises, to do the Kaiser's to do the projects that's the second factor.

Interviewer: So what's your opinion about that, do you think Lean Six Sigma, affect the company adhering to this regulatory policy?

Interviewee 4: Absolutely. And I've actually Yeah, one of my previous roles as well, we did have an issue with GDP, compliance in terms of GDP accuracy, and completeness of records. So we were running as you know, in the medical device sector, you have to review your paperwork twice your completed. So you have to have an operations review of an SSP, and then you have to have a quality review, of an SSP. So as far as the particular problem, that was a huge business risk production company at the time. So what I did is, I used, we call it root cause analysis to try and understand why we were getting so many errors. And what I found is the documents weren't designed correctly, they were asking to pick up redundant data. And there was a lot of duplication. There was also no ownership as to who was to fill out the paperwork. And because it was cross shift, and again, it was it was even less clear who was the person who extracted the work apart from the person who finished the work to sign the record. So what I did was able to record this, and I brought it down to a number of factors, and I was able to track stocks and displays over runtime charts. We were also able assign the owner of the error so we were able to understand who made the error or the omission. And we were able to target that person then for awareness of what the expectations were from them. But also to set the culture that, you know, there's a focus on this, it's important, it needs to be done. And, you know, if you're not doing this, and, you know, your supervisor will be talking to you to help you out and to understand why you're not able to fill out your paperwork. So as to back it up, and we created the awareness. And then I redesigned all the documents so that they were no longer picking up redundant information and it was easier for document owner to fill it out chronologically, for the first piece of information you require to record was the first piece of information that happened during that process. So that was just looking at 5 Whys, root cause analysis,

and voice of customers as well, so we actually had a workshop a number of workshops with the core team and product and line supervisors so we were able to bring BSP accuracy from about the mid 60s up to the low 90% within four months.

Interviewer: A slight question is that does voice customer matrix actually help solve customer complaints, like how effective is it from your perspective?

Interviewee 4: I would use the voice of customer up front Rachel I'd actually use that to develop the specifications when I'm developing a process or a product or service and the most important part is to understand for both parties quality is expected of each other. So I would go to the customer and not necessarily be an external customer could be an internal customer within your own factory and ask you what exactly do you need and I would look at it I would also put that together with the side pocket chart with suppliers input process output customer to make sure you have you asked all your stakeholders to be included on the voice of customer. So out of that you can have an explicit document you know the link has to be this the specificity dimensions have to be that the timing has to be this you know it all very explicit quite requires. Now within that the voice of customer there are two types of requirements so to the Express requirements which is easy to write down you ask them it's written on paper, but there's also the inferred requirements. So, you know the customer always to expect you to produce this at an ISO standards because your ISO certified they may not necessarily write it down so that can be the difficult part being the inferred requirements. So when there is a customer complaint I would more so be focused on what the specifications were rather than the voice of customer. So if I did get a complaint we understand fully what the complaint is from the customer pull up the specifications and say listen can you show me where the air is first of all where and I will not meet specification then if the complaints wasn't explicitly call out he could upheave your customer specification and to include that but first of all you need to understand the impact to cost and add to the process.

Interviewer: Do you have a certification Lean Six Sigma?

Interviewee 4: I have a green belt in Lean Six Sigma from Boston Scientific and black belt with an American crap I can't remember. I have a specialist degree in Lean thinking.

Interviewee 5: To my basic knowledge none that I know off because eh Lean Six Sigma is working in the company absolutely fantastically well and I actually just started working here five months ago and with the level of implementation that has gone on and I think it's like working very well.